Frequency of Intraocular Lens Dislocation and Pseudophacodonesis, 20 Years After Cataract Surgery – A Prospective Study

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• PURPOSE: To examine the incidence and trends of late intraocular lens (IOL) dislocation/decentration and the frequency of pseudophakodonesis.
• DESIGN: Prospective, population-based cohort study.
• METHODS: A total of 800 patients were examined before cataract surgery in 1997-1998. Twenty years later, 100 of 133 survivors (75%) participated in the follow-up. An eye examination was performed including assessment for pseudophakodonesis and dislocation of the IOL. The medical records of all included patients at baseline were studied. Main outcome measures were previous IOL exchange or repositioning surgery, significant IOL dislocation, degree of pseudophakodonesis, and visual acuity.
• RESULTS: Twenty years after the original cataract surgery, 10 of the 800 patients at risk (1.2%) had needed dislocation surgery. Before cataract surgery, 39% of all patients had pseudoexfoliations (PXF). Mean time from cataract surgery to dislocation surgery was 12 years 6 months (range 3 years 9 months to 19 years 3 months). The cumulative incidence over 20 years was 6% in patients with PXF and 2% without PXF at surgery ($P = .035$). Mean age at cataract surgery in the 10 dislocated cases was 68.3 years (range 58-80). Twenty years after surgery, 5 of 98 (5%) patients had moderate/pronounced pseudophakodonesis.
• CONCLUSIONS: In this population-based cohort, the 20-year cumulative incidence of IOL dislocation needing surgical attention was significantly higher in patients with PXF than without PXF before surgery. The individual patient seems to have a low risk of being affected by this complication, but dislocated IOLs may cause a relatively large public health care burden, because of the large number of people in society with previous cataract surgery. (Am J Ophthalmol 2019;198:215–222. © 2018 Elsevier Inc. All rights reserved.)

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POSTERIOR CHAMBER INTRAOCULAR LENS (IOL) dislocation or decentration is a well-known late complication following cataract surgery. After retinal detachment, it is the second most frequent major complication following cataract surgery.[1] Over the past decades dislocation/decentration has also been the most common complication and reason for IOL explantation.[2–4] Several studies have reported an increasing trend in recent years,[1,5–7] and IOL dislocations are among the few major complications that have increased since 1995. Low case numbers complicate statistical comparisons and short follow-up makes it difficult to examine trends over time.

Late dislocation is defined as occurring 3 months or more after cataract surgery, and is generally associated with conditions of zonular weakness, rather than inadequate IOL fixation.[1] Pseudoexfoliation (PXF) is the most common condition, followed by prior vitreoretinal surgery.[8,9] Most commonly the IOL dislocation is spontaneous and within the intact capsular bag.[10,11]

In a population-based study 10 years after uneventful cataract surgery, the mean time for those needing dislocation surgeries was 6.3 years.[5] There are concerns of an impending epidemic of IOL dislocations. This is owing to the relatively long time frame for this complication to appear and the large number of people who have undergone cataract surgery.[12,13] The issue of decentration is also important because of the increasing use of wavefront-corrected IOLs, which require excellent centration to maximize the visual outcome.[14,15]

A dislocated IOL often requires explantation/exchange or repositioning with or without suturing because of potential complications, such as decreased vision, rising intraocular pressure, retinal tears, rhegmatogenous retinal detachment, and vitreous hemorrhage.[9,10] However, patients with IOL dislocation associated with PXF and no other comorbidity have the potential for excellent visual outcome with a minimum of intraoperative and postoperative complications.[9] The outcome for patients with other etiologies that cause the dislocation depends on the comorbidity involved.

The aims of this paper were to prospectively estimate the cumulative incidence and trends of late IOL dislocation and the rate of pseudophakodonesis and significant IOL decentration in a population-based cohort of cataract

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surgery cases. The patients were followed from preoperatively to 20 years after surgery.

PATIENTS AND METHODS

• **STUDY DESIGN:** The study is a prospective, observational, population-based cohort study. The tenets of the Declaration of Helsinki were followed and prospectively approved by the local ethics committee. The local ethics committee of Umeå University, Sweden, approved the study design and all details of the study. Informed consent was obtained from all patients who participated in the study.

• **PATIENT COHORT:** All patients who underwent cataract surgery with IOL implantation during a 1 year period (1997-1998) at Norrlands University Hospital in Umeå, Sweden, were prospectively registered (n = 897). Those who had cataract surgery combined with other ocular surgery or surgical indications other than restoring vision, or who died before the first follow-up at 1 month, were excluded (n = 55).

Thirty-two patients were lost to follow-up or declined to participate and 810 patients remained in the study. Ten patients with less risk for IOL decentration (ie, anterior chamber IOL and sutured IOL on the day of cataract surgery) were also excluded from the study. The original cohort from 1997-1998 represents 800 patients at risk for dislocation. Patients who had undergone surgery in both eyes during the period studied were included as 1 patient, and data from only the first surgical event were included in the analysis. Detailed methods of this cohort, inclusion and exclusion criteria, dropouts, and 5-, 10-, and 15-year results have previously been published.[5,16,17] The number of residents who underwent surgery in other districts was negligible because of the Swedish Social Security regulations at the time of the study. Four surgeons performed all the surgical procedures.

Twenty years after surgery, 133 of the 800 patients (17%) were still alive. All survivors were offered an eye examination, and 100 (75% of survivors) participated. Of the 33 patients unable to participate, 9 suffered from dementia (27%); 23 (70%) declined participation because of trouble/unwillingness to travel to the clinic, either because of illness or reluctance to travel the long distance to the clinic; and 1 (3%) could not be located.

• **EXAMINATION BEFORE SURGERY, POSTOPERATIVELY, AND AT 5, 10, 15, AND 20 YEARS AFTER SURGERY:** A few weeks before surgery, approximately 1-2 months after surgery, and at 5 years after surgery, all patients underwent a routine eye examination with measurement of best-corrected visual acuity (BCVA) and dilation in a standardized manner. The presence of any ocular comorbidity or past surgery was recorded.

At 10, 15, and 20 years after surgery the patients underwent the same standardized eye examination, which was performed preoperatively, postoperatively, and at 5 years after the surgery. In addition, the centration of the IOL was visually assessed and graded at the slit lamp using the dilated pupil as a reference. A decentration of at least 2 mm in any direction was classified as significant. If there were no obvious signs of pseudophakodonesis, the patients were asked to gaze upward quickly, to wait 5 seconds, and then to gaze downward quickly to induce movements of the IOL. Pseudophakodonesis was graded by 1 surgeon (E.M.) as none, slight/minor (barely discernible), moderate (obvious), or pronounced (looks like it will immediately drop into the vitreous).

Patients who did not participate with the follow-up examinations had their records checked, to determine if any IOL exchange or repositioning surgery had been performed up to 20 years since the cataract surgery in 1997-1998. For the same reason, the records were also checked for the patients who died between 10 and 20 years after surgery.

• **STATISTICAL METHODS:** Independent sample *t* tests were used to compare age differences between male and female patients. The Fisher exact test or χ^2 tests were used to analyze the 2-by-2 tables. The Mann-Whitney *U* test was used to calculate the difference in final postoperative BCVA between the IOL exchange patients and the patients with reposition surgery.

Life table calculations were made to calculate the 20-year cumulative incidence of IOL dislocation needing surgical attention, and Kaplan-Meier plots were used to compare the cumulative incidence of dislocation surgery between patients with and without PXF at cataract surgery. The difference between the curves was tested using the log-rank test. Statistical analyses were performed using IBM SPSS Statistics software (version 24.0; IBM Corp, Armonk, New York, USA).

RESULTS

• **DEMOGRAPHICS, TYPE OF SURGERY, AND INTRAOCULAR LENS IMPLANTED:** Twenty years after cataract surgery a total of 100 patients were examined; 34 (30%) were male (mean age 77.2 years; standard deviation [SD] =11.5) and 66 were female (mean age 81.0 years; SD = 9.8). The age difference was not statistically significant ($P = .09$).

At the time of cataract surgery in 1997-1998, 39% (309/800) of all patients originally included had detectable PXF, compared with 14% of the patients examined at 20 years (14/100).

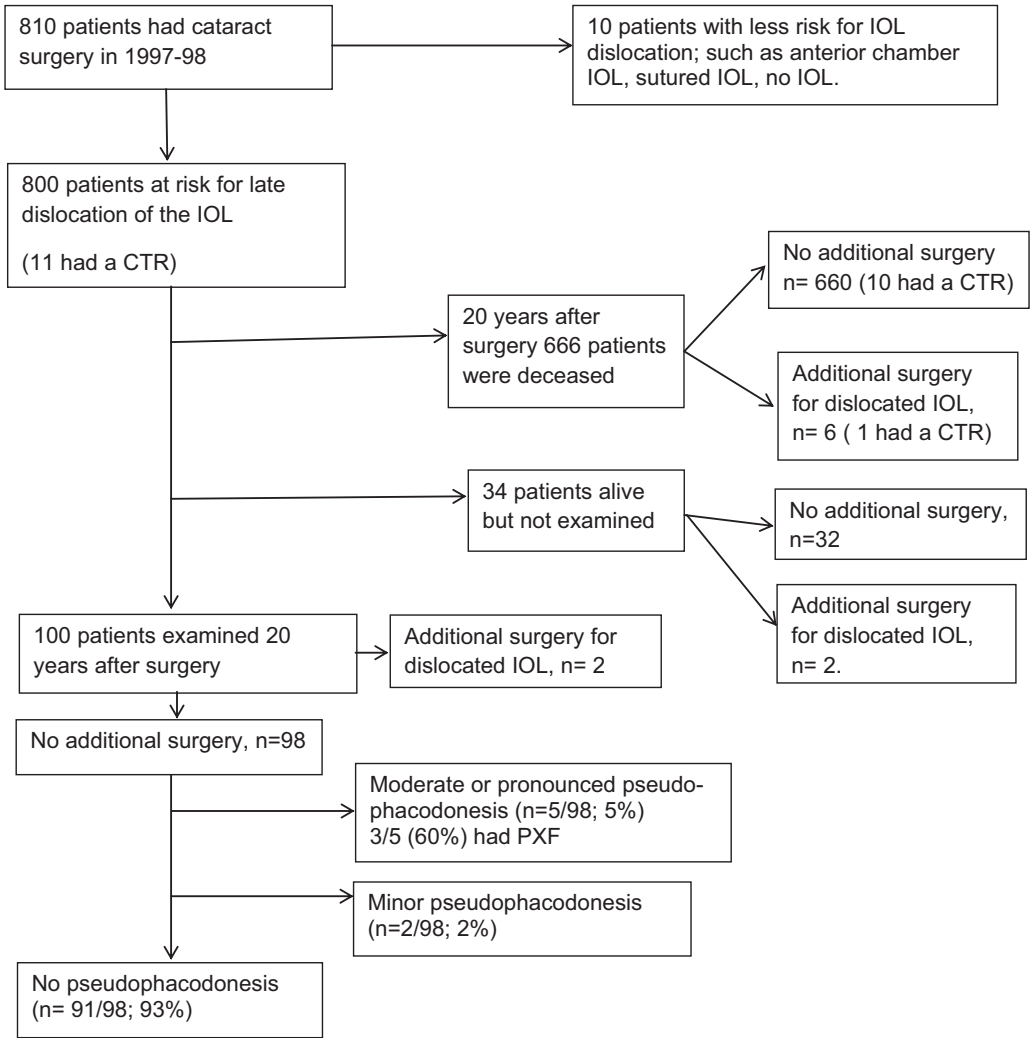

FIGURE 1. Flowchart showing the longitudinal outcome of intraocular lens (IOL) dislocation and pseudophacodonesis up to 20 years after surgery. Additional surgery refers to all types of dislocation surgery, such as suturing of the IOL, IOL exchange, or repositioning. The patient without light perception who had no dislocation surgery is included as a surgical event at the time the dislocation was diagnosed, as surgery would have been performed if the eye had useful vision. CTR = capsular tension ring; PXF = pseudoexfoliations.

All examined patients had a sutureless clear corneal phacoemulsification with a 3.2-mm temporal incision and foldable IOL. The complication rate (capsular/zonular damage) was 2% (2/100). Most of the patients (93/100; 93%) had a 3-piece Alcon MA60BM AcrySof IOL implanted.

• **20-YEAR INCIDENCE OF INTRAOCULAR LENS DISLOCATION NEEDING SURGICAL INTERVENTION:** Figure 1 shows a flowchart of the longitudinal 20-year outcome of IOL dislocation and pseudophakodonesis.

Of the 800 patients at risk, 10 patients (1.2%) had late IOL dislocation that needed surgical attention at some point up to 20 years after the initial surgery. Table 1 shows the demographics of these 800 patients in relation to the occurrence of PXF before cataract surgery. The significantly higher proportion of female patients affected with PXF can be explained by the fact that the women were significantly older than the men.

Table 2 shows the demographic and clinical patient data for all patients from the original cohort (1997-1998) with dislocation of the IOL needing surgical intervention. All these patients had IOL dislocation within the bag and none had IOL dislocation alone (ie, without significant capsule complex dislocation). None of the patients had a history of ocular trauma before or after the cataract surgery. There was a higher percentage of male (6/10; 60%) than female patients (4/10; 40%) who needed dislocation surgery. However, this difference was not statistically significant comparing with the male-to-female ratio when the study started in 1997, $P = .09$.

TABLE 1. Demographics at the Time of Cataract Surgery (1997-1998) of the 800 Patients at Risk for Dislocation Surgery, and Distribution of Pseudophacodonesis 20 Years After Surgery in Relation to Occurrence of Pseudoexfoliations Before Cataract Surgery

	Total	PFX at Surgery	No PXF at Surgery	*P* Value
Number of patients (% of total patients)	800	309 (39%)	491 (61%)	
Mean age (SD), years	74.7 (10.7)	78.6 (6.7)	72.2 (11.9)	.0001*
Sex (% male)	36	31	38	.026*
Number of patients needing dislocation surgery (%)	10 (1.2%)	5 (1.6%)	5 (1.0%)	.46
Pseudophacodonesis observed 20 years after surgery				
Number of patients	98	14	84	
Without pseudophacodonesis	91	10	81	
With pseudophacodonesis (% of total patients)	7 (7.0%)	4 (29.0%)	3 (4.0%)	.0008*

PFX = pseudophacodonesis.
P values indicated by an asterisk (*) are statistically significant.

The mean age when the cataract surgery was performed in 1997-1998 was 71 years in male patients and 65 in female patients, $P = .17$. Of the 11 patients who had a capsular tension ring (CTR) at the cataract surgery 1 (9%) had late dislocation within the bag of both the IOL and CTR. One patient (of 10) with indication for surgery had no dislocation surgery because VA was no light perception caused by glaucoma.

The time lapse from cataract surgery to the date of dislocation surgery ranged from 3 years 9 months to 19 years 3 months (mean 12 years 6 months).

The 20-year cumulative incidence for needing dislocation surgery was 3% in the total patient group. Figure 2 shows the cumulative incidence over 20 years in the 2 patient groups, PFX and no PFX, before cataract surgery. The 20-year cumulative incidence for need of dislocation surgery was 6% in the PFX group and 2% in the no PXF group ($P = .035$). The majority of all patients (99%; 790/800) had not needed surgery for dislocated IOL 20 years after cataract surgery and there were no sex-related differences ($P = .2$).

There was no significant difference in final postoperative BCVA between the IOL exchange patients (range 20/21 to 20/32) and the patients with reposition surgery (range 20/22 to 20/58) ($P = .42$, Table 2).

The size of the capsular opening was neither measured during surgery nor postoperatively. However, none of the 800 patients of the original patient cohort had capsular contraction syndrome to such a degree that radial neodymium:yttrium–aluminum–garnet (nd:YAG) laser anterior capsulotomy was necessary.

• **CHANGE IN PSEUDOPHACODONESIS FROM 10 TO 20 YEARS:** At the examination 20 years after surgery 93% (91/98) of the patients had no pseudophacodonesis (PD). Figure 1 shows the distribution of patients in relation to degree of PD. Only a small percentage of the patients had moderate or pronounced PD (5/98; 5%), and of those 5 patients, 3 had PXF. Table 1 shows the distribution of PD in this patient group in relation to occurrence of PXF before surgery. There was a significantly larger proportion of patients with PXF before surgery who had PD 20 years after cataract surgery ($P = .0008$).

The 93 patients who had not undergone dislocation surgery at 10 years were examined at 10 years, as well as at 15 ($n = 89$) and 20 years, after surgery. Figure 3 shows the change in degree of PD found 10 years after surgery compared with the findings 15 and 20 years after surgery. Eight percent of the patients (7/93) had more pronounced PD or had dislocation surgery 20 years after cataract surgery.

• **DECENTRATION OF THE INTRAOCULAR LENS:** In 95 of 100 patients (95%), there was no significant decentration of the IOL 20 years after surgery. Significant decentration (2 mm or more) was observed in 5% of the patients (5/100); of those 5 patients, 4 had PXF. Decentration downwards and/or nasally was most common.

DISCUSSION

TWENTY YEARS AFTER CATARACT SURGERY, THE TOTAL number of patients who needed exchange or repositioning surgery remained low in this prospective population-based cohort with a preoperatively high frequency of PXF. Patients with PXF at cataract surgery had a significantly higher incidence of dislocation surgery than patients with no PXF. This difference in incidence was detectable as early as 4 years after cataract surgery (Figure 2). As reported in previous research, the cumulative incidence increases steadily during the observation period.[7,12] The mean time from cataract surgery to reposition surgery in a cohort or case series seems to depend on the length of the follow-up time, and the increase in cumulative incidence is

TABLE 2. Demographic and Clinical Data of All Patients From the Original 1997-1998 Study Cohort (N = 800) Who Needed or Had Undergone Intraocular Lens Dislocation Surgery

Patient No.	Age at Cataract Surgery (Years)	Sex	Time from Cataract Surgery to Dislocation	Predisposing Condition/ Comorbidity	Nd:YAG	IOL Type/CTR	Surgical Intervention	Final BCVA, logMAR (Snellen)[a]
1	75	M	3 years, 9 months	PXF	Yes	3-piece Alcon MA60BM	Exchange to sclerally sutured IOL	0.14 (20/29)
2	72	M	4 years	PXF and asteroid hyalosis both eyes had IOL luxation	No	3-piece Alcon MA60BM + CTR Morcher[b] Model x14	exchange to sclerally sutured IOL and vitrectomy	0.02 (20/21)
3	73	M	6 years, 5 months	Unknown	No	3-piece Alcon MA60BM	Reposition and suture of the original IOL	0.22 (20/33)
4	70	F	9 years, 9 months	PXF	Yes	3-piece Alcon MA60BM	No surgery	No light perception
5	80	M	9 years, 10 months	PXF and high myopia (AL = 28.63 mm)	No	1-piece PMMA Pharmacia 812A	Exchange to sclerally sutured IOL	0.2 (20/32)
6	69	F	9 years, 11 months	Previous vitrectomy and myopia, AL 25.78 mm; both eyes had IOL luxation	Yes	3-piece Alcon MA60BM	Reposition and 1 suture of the IOL	0.1 (20/25)
7	62	F	12 years, 3 months	PXF	No	3-piece Alcon MA60BM	Reposition and suture of the IOL	0.22 (20/33)
8	62	M	16 years, 7 months	Uveitis	No	3-piece Alcon MA60BM	Reposition and suture of the IOL	0.05 (20/22)
9	58	F	16 years, 6 months	Myopia (AL 25.41 mm)	No	3-piece Alcon MA60BM	Reposition and suture of the IOL	0.15 (20/29)
10	64	M	19 years, 3 months	Unknown	Yes	3-piece Alcon MA60BM	Reposition and scleral fixation of IOL (tunnel)	0.46 (20/58)

AL = axial length; BCVA = best-corrected visual acuity; CTR = capsular tension ring; IOL= intraocular lens; nd:YAG = neodymium:yttrium–aluminum–garnet laser capsulotomy; PMMA = polymethyl methacrylate; PXF = pseudoexfoliations.

[a]Final BCVA was defined as BCVA at the latest follow-up in the study or, in cases in which the patients had no study-related follow-up, from the patient records.

[b]Morcher GmbH, Stuttgart, Germany.

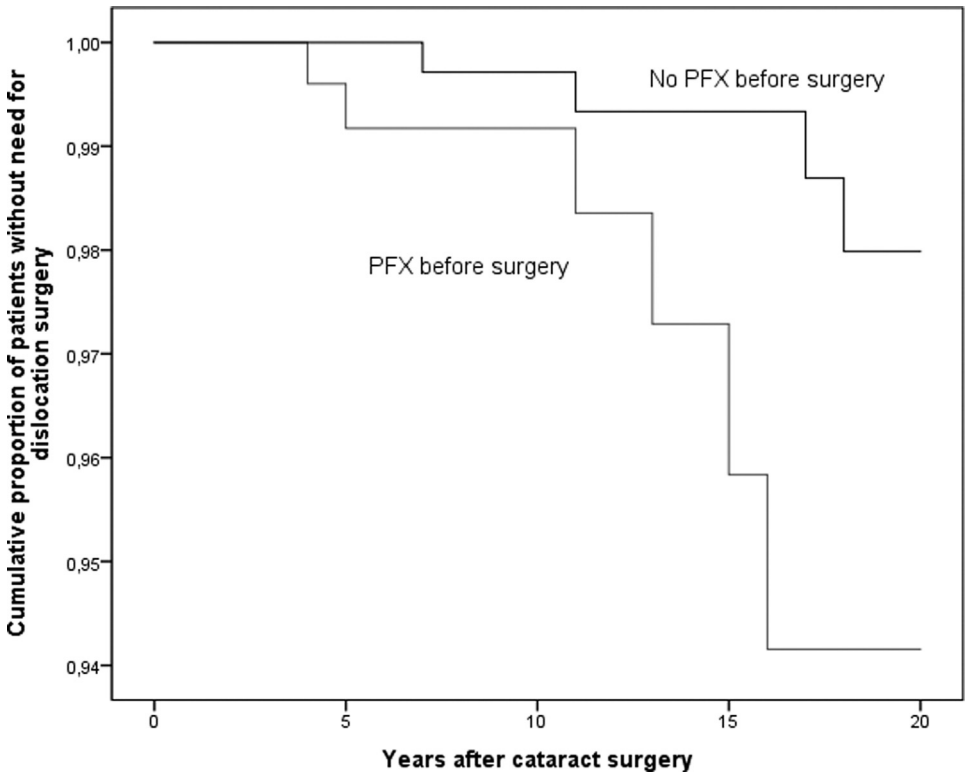

FIGURE 2. Survival curves show the cumulative 20-year incidence of not needing surgical attention because of intraocular lens dislocation in the 2 patient groups, pseudoexfoliations (PFX) and no pseudoexfoliations (no PFX), before cataract surgery.

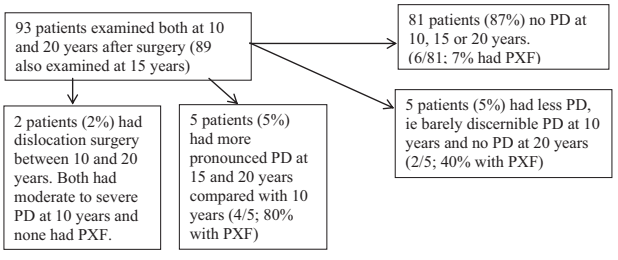

FIGURE 3. Change in pseudophacodonesis (PD) from 10 to 20 years after surgery. The percentage of patients with pseudoexfoliations (PXF) was based on the clinical examination before surgery.

primarily the result of the longer duration of pseudophakia in the population. The degree of pseudophacodonesis assessed at 20 years after surgery suggests a forthcoming need for dislocation surgery, even later than 20 years after surgery, especially for PXF patients still alive.

In a retrospective study, Dabrowska-Kloda and associates[6] reported the cumulative risk for IOL dislocation at 5, 10, 15, and 20 years after cataract surgery to be 0.09%, 0.55%, 1%, and 1%, respectively. Another retrospective study found that at 10, 20, and 25 years after cataract surgery the cumulative risk for dislocation was 0.1%, 0.7%, and 1.7%, respectively.[12]

A retrospective Canadian population-based analysis included all secondary IOL procedures, such as exchange, repositioning, and explantation. The 5-year incidence was 0.78%-0.93%, but that study also included indications such as undesirable refractive outcome and dissatisfaction with multifocal IOLs.[13] The high frequency of PXF in the population of northern Sweden, together with the significantly higher cumulative incidence in need for dislocation surgery found in PXF patients, explains the much higher total risk of IOL dislocation, 3% over 20 years found in the present study.

PXF is the most common predisposing condition associated with late IOL dislocation.[8,10] It has been estimated that 20% of the population older than 60 years in the general population worldwide have PXF.[18] In many parts of the world, the percentage of cataract cases with PXF is far higher than 20%, and the prevalence also increases with age.[5,19] Preoperatively (ie, 20 years earlier), 39% of the study patients had detectable PXF.[5] As the remaining patients in the study are 20 years older than at the examination in 1997-1998, some of the patients who had no PXF preoperatively inevitably develop PXF-related laxity of the zonular fibers. In many cases, after cataract surgery the clinical detection of PXF is less obvious. Thus, the prevalence of PXF might actually be higher in late postoperative dislocation, as has been suggested.[9] Previous studies that have examined dislocated IOLs have found the presence

of PXF material on the capsular bag without any clinical history of PXF, and it has been estimated that 50% of PXF cases might be clinically undetected.[2,20]

In the present study, 50% of the patients who needed surgery for IOL dislocation had PXF before surgery. In 2 patients the reason for dislocation was unknown but might have been owing to undetected PXF-related zonular laxity, which developed after cataract surgery. Nevertheless, the present study shows that patients with PXF diagnosed before cataract surgery have a significantly higher risk for IOL dislocation than patients who had no detectable PXF at surgery. It is possible that patients who develop PXF later may have less risk of dislocation. However, long duration of detectable PXF may progressively increase the laxity of the zonulae and the risk for IOL dislocation.

Another reason for a high cumulative incidence of dislocation surgery in the present study might be the prospective design and the low number of dropouts. All patients had surgery at 1 clinic, both the cataract surgery 20 years earlier and the dislocation surgery. Only patients with in-the-bag IOL after phacoemulsification surgery were included to avoid bias caused by a large number of extracapsular cataract surgery patients in the cohort, as this technique was common around the 1980s.

The visual outcome after the second surgical procedure was generally good, which is consistent with previous studies.[2,7,11] There was no significant difference in final VA between patients with reposition surgery and exchange surgery in the study, but the patients in each group were few.

The IOL material and type might play a considerable role in capsular fibrosis and gross capsular contraction. The progressive weakness of the zonular fibers in association with capsular bag contraction is an important issue in the development of late dislocation. Among the various types of foldable IOLs, the acrylic 3-piece hydrophobic IOL induces less capsule contraction and offers more resistance to contraction of the bag compared with the 1-piece acrylic IOLs.[2,7,11,12] Most patients in the present study had a 3-piece hydrophobic acrylic IOL implanted (Alcon MA60BM; AcrySof). Today, the major type of IOL implanted is the 1-piece IOL, which might increase the need for dislocation surgery in the future.

The use of CTRs has been advocated as a prophylactic procedure to prevent spontaneous dislocation of the IOL–capsular bag complex in patients with PXF or other types of zonular weakness.[21–23] No long-term prospective studies have been performed to confirm this contention.

In the present study a CTR was routinely implanted when the surgeon judged it necessary—that is, with intraoperative zonular weakness or zonular rupture to such a degree that the future stability of the IOL was believed to be at risk. Eleven of 800 patients (1.4%) had a CTR implanted during surgery, which is a low number, considering the high frequency of PXF in the population. It is difficult to know if the number of dislocations in the study population would have been lower if a larger number of CTRs had been implanted at surgery.

To the author's knowledge, there is no other study published that prospectively follows and examines cataract surgery patients this long. Population-based studies with a 20-year follow-up are comparatively easy to perform in Sweden. It is important to obtain low numbers of dropouts to reduce selection bias and to increase the validity of the results. The low incidence of complications makes population-based longitudinal studies the best model to evaluate surgical outcomes after cataract surgery.

Another strength of this study is the single-payer universal healthcare system in Sweden, which captures patients across all institutions in the area and at every stage of their care. The risk of cataract patients being operated outside county borders was negligible.

There was a higher percentage of male than female patients who needed IOL exchange or repositioning surgery, which is consistent with previous research.[11,13] This is difficult to explain, but men are more prone to ocular trauma that might have happened decades earlier and had been forgotten by the time of cataract surgery.

In conclusion, in-the-bag IOL dislocation or decentration is a late complication of cataract surgery more likely to occur in certain predisposed eyes. The cumulative incidence of IOL exchange or repositioning 20 years after cataract surgery was low in total number of patients affected, even though this population had a high incidence of PXF. Patients with PFX at cataract surgery have a significantly higher cumulative incidence of dislocation surgery than patients without PXF. Prognosis after treatment is generally favorable. However, the potential burden to society caused by dislocated IOLs that needed surgical attention is relatively large because of the vast number of people worldwide with previous cataract surgery.

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