Original Article

Visual outcomes and complications of manual small-incision cataract surgery in patients with pseudoexfoliation

Chandrashekharan Shivkumar, Mobin Gadiwan, Madhumita Rout, Aditi Ghosh, Sherin Haroon, Rengappa Ramakrishnan[1]

Purpose: Pseudoexfoliation is an age-related fibrillopathy characterized by the deposition of fibrillar material in the eye with an increased risk of complications during cataract surgery. Aim was to study visual outcomes and complications in patients with pseudoexfoliation undergoing manual small-incision cataract surgery (MSICS). **Methods:** Prospective observational study was performed on 152 patients with pseudoexfoliation above 50 years undergoing MSICS in a tertiary hospital from December 2016 to November 2017. Intraoperative and postoperative complications were documented with follow-up on postoperative day 1, 1st week, 1st month, and 3rd month. **Results:** Preoperative small pupil was noted in 49 eyes (32.2%), and 19 (12.5%) required intraoperative measures. Intraocular complications noted were zonular dialysis in five (3.3%), posterior capsular rupture in one (0.7%), and iridodialysis in one (0.7%). On postoperative day 1, the most common complication was corneal edema in 134 patients but clinically significant in only 23 (15.1%). Postoperative complications at 3 months were irregular pupil in 17 cases and decentered IOL in three cases. Intraocular pressure decreased with each visit [preoperative mean: 14.39 (±3.4) and 13.37 (±2.0) 12.53 (±1.4) mm Hg at 1 and 3 months, respectively]. There was a significant improvement in vision from the first day mean pinhole vision of 0.26 (±0.24) to mean best corrected visual acuity (BCVA) of 0.09 (±0.22) and 0.07 (±0.22) at 1 and 3 months, respectively. Mean endothelial cell loss was 193.16 (7.79%) and 266.01 (10.68%) at 1 and 3 months, respectively. **Conclusion:** Pseudoexfoliation has an increased risk of complications during cataract surgery. MSICS gives good outcomes in terms of visual recovery and postoperative outcomes.

Key words: Cataract surgery and pseudoexfoliation, cataract surgery outcomes in pseudoexfoliation, complications of cataract surgery, manual small-incision cataract surgery, MSICS in pseudoexfoliation

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Pseudoexfoliation, first described by Lindberg in 1917, is an age-related genetically inherited fibrillopathy characterized by gradual synthesis, accumulation, and deposition of abnormal fibrillar extracellular material involving the anterior segment of the eye and other organs.[1] The reported prevalence rate of pseudoexfoliation varies from as low as 0.4% among the Chinese population to as high as 6.45% in the Pakistani population and 3.8% in the rural south Indian population.[2-4]

Significantly greater risk of complications during cataract surgery such as posterior capsular rupture, zonular dialysis, and hyphema has been reported. According to Thevi *et al*.[5] and Scorolli *et al*.,[6] the likelihood of intraoperative complications is 2.68–5 times greater compared to normal eyes. Most of the complications are mainly believed to be caused by surgical trauma resulting from iris vessel pathology and insufficiently dilated pupil.[7,8]

The outcome of surgery with respect to visual acuity is variable due to the abovementioned intraoperative complications and thus necessitates proper perioperative strategies. The immediate postoperative period is also fraught with complications, mainly corneal epithelial and stromal edema, which are more frequent than in normal cataracts. Increased intraocular pressure (IOP), secondary glaucoma, and decentration of intraocular lens (IOL) are other complications.

Late postoperative complications mainly include progressive weakness of the zonules, decentration and dislocation of the IOL, and decompensation of the corneal endothelium. Miyake *et al*.[9] observed a decrease in the hexagonality and an increased coefficient of variation in the corneal endothelial cells in patients with PXF. It has been assumed that these changes represent an abnormal and unstable endothelium, predisposing it to endotheliopathy.

As reported by Shastri *et al*.,[10] there could be good outcomes and fewer complications in patients with pseudoexfoliation

Department of Cataract and IOL Services, Aravind Eye Hospital and Post Graduate Institute of Ophthalmology Tirunelveli, Tamil Nadu, [1]Department of Glaucoma Services, and Advisor Aravind Eye Hospital and Post Graduate Institute of Ophthalmology, Tirunelveli, Tamil Nadu, India

Correspondence to: Dr. Chandrashekharan Shivkumar, Aravind Eye Hospital and Post Graduate Institute of Ophthalmology, S. N. High Road, Tirunelveli, Tamil Nadu – 627 001, India. E-mail: shiv_shekhar@yahoo.com

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undergoing phacoemulsification by experienced surgeons. Haripriya *et al*.[11] reported that phacoemulsification in pseudoexfoliation eyes without shallow anterior chamber or zonulopathy did not carry an increased risk of complications. However, in cases with advanced pseudoexfoliation and with relatively inexperienced surgeons, manual small-incision cataract surgery (MSICS) may be safer.

Hence, the aim of this study was to analyze the visual outcomes, intraoperative complications, and postoperative complications of MSICS in patients with cataract and pseudoexfoliation.

Methods

This was a prospective observational study of patients presenting with cataract and pseudoexfoliation and undergoing MSICS with polymethyl methacrylate (PMMA) IOL implantation at a tertiary eye care center in South India.

The study was approved by the institutional ethics committee and was conducted in accordance with the tenets of the Declaration of Helsinki. The study was conducted from December 2016 to November 2017 with a 9-month recruitment period and 3 months of follow-up.

Patients above 50 years of age belonging to either gender diagnosed to have cataract with pseudoexfoliation detected on slit-lamp examination before and after pupillary dilatation, posted for MSICS, and willing to participate in the study were included.

Patients with the following conditions were excluded: age > 80 years, traumatic cataracts, congenital cataracts, complicated cataracts, uveitic cataracts, corneal scars, previous ocular surgeries, vision impairing retinal pathology, uncontrolled systemic conditions such as diabetes, and monocular patients.

With the assumption of 5% precision, 95% confidence interval, 10% intraoperative complications (Hemalatha[12]), and 10% dropout, the sample size was calculated as 152 (138 + 14). In total, 152 patients were included in the study and were followed up for 3 months from surgery (first day, 1 week, 1st month, and 3rd month).

Preoperative examination included a detailed history of presenting complaints and slit-lamp examination to note the status of the cornea, depth of anterior chamber, structures on which pseudoexfoliative material was deposited, size of pupil on maximum mydriasis, type of cataract and grade of nuclear sclerosis, and presence of iridophacodonesis. Posterior segment examination was done with 90-D when possible and with ultrasound B-scan when the viewing of the retina was not possible. Indirect ophthalmoscopy as per protocol was done only in patients with an axial length of more than 26 mm. Investigations included estimation of the intraocular pressure (IOP) with Goldman applanation tonometry, IOL power measurement (by manual keratometry and ultrasound biometry), and specular microscopy (SP3000P, Topcon) to note the preoperative endothelial status.

All patients underwent MSICS by a single senior surgeon with an experience of more than 10,000 surgeries.

Surgical procedure

Prophylactic ofloxacin eye drops 0.3% were started 1 day before surgery and continued postoperatively. On the day of surgery, the pupil of the eye to be operated was dilated adequately with a combination of 0.8% tropicamide and 5% phenylephrine eye drops (tropicamide 1% in hypertensive and cardiac patients) every 10 min thrice before surgery. Flurbiprofen 0.03% was instilled thrice one day before surgery and four times half hourly immediately before surgery.

All surgeries were done under subTenon's or peribulbar injection of lignocaine 2% mixed with 1500 units of hyaluronidase with/without adrenaline 1:200000. After aseptic precautions and draping the patient's eye, the maximum pupillary diameter achieved pharmacologically was noted. A routine MSICS was performed through a self-sealing sclerocorneal tunnel, with implantation of the IOL in the capsular bag or in the sulcus if the need arose. Adequate viscoelastics were used to protect the corneal endothelium, and at the end of the surgery, it was thoroughly washed out. Intracameral moxifloxacin 0.1 mL (500 mcg) was injected at the end of the surgery.

In the event of a complication during surgery, the case was appropriately managed (capsule tension ring (CTR) in case of weak zonules or zonular dialysis, anterior vitrectomy when needed in cases of zonular dialysis or posterior capsular rupture, and placement of 3-piece IOL in the sulcus).

The following intraoperative details were noted: the size of the pupil at the start of the surgery, type of viscoelastic used, pupil expansion measures if taken, any weakness of zonules or phacodonesis signified by wrinkling of the anterior capsule during initiation of the continuous curvilinear capsulorhexis (CCC), any intraoperative complication, additional procedures such as implantation of CTR, and whether anterior vitrectomy was done in case of capsular complications.

On the next postoperative day, uncorrected visual acuity (UCVA) and improvement with pinhole, status of the wound, presence and grade of corneal epithelial and stromal edema, anterior chamber reaction, presence of fibrinous uveitis, and position and centration of the IOL were noted.

Postoperatively, patients received topical antibiotics (ofloxacin 0.3%) for 2 weeks and Prednisolone acetate 1% on a tapered schedule for 6 weeks. Those with stromal corneal edema received the above along with a topical hyperosmotic agent such as 5% sodium chloride solution, and those with epithelial edema received anti-glaucoma treatment – usually timolol maleate 0.5% or betaxolol 0.5% and acetazolamide tablets, if not contraindicated. Patients with iritis received cycloplegics (homatropine 1%) for 2 weeks. In cases with intraoperative capsular complications, an oral antibiotic (ciprofloxacin 500 mg twice a day for 5 days) was added as per protocol to prevent endophthalmitis.

Resurgeries done for hyphema, residual cortex, or decentered or dislocated IOLs were noted.

Patients were followed up at 1 week, 1 month, and 3 months.

Results

Out of 152 patients, 59 (38.8%) were males and 93 (61.2%) were females. The mean age was 67.38 years (range: 45–79 years). In

28 (18.42%) cases, the distribution of pseudoexfoliative material was unilateral and bilateral in 124 (81.58%).

In our study, 88 (57.89%) patients had immature cataract with nuclear sclerosis grade 2 or 3, 41 (26.97%) had mature cataract, 17 (11.19%) had brown cataract, three (1.97%) had hypermature cataract, two (1.32%) had phacolytic glaucoma, and one (0.66%) had black cataract.

All 152 patients had pseudoexfoliative material on the pupillary border and on the peripheral anterior capsule, four (2.6%) patients had pseudoexfoliative material on the central zone, 19 (12.5%) patients on the corneal endothelium, 18 (11.8%) on the trabecular meshwork, 16 (10.5%) on the iris surface, and 15 (9.9%) on the zonules in the eye to be operated.

The sequelae of pseudoexfoliation in the eye to be operated are shown in Table 1, the most common being small pupil following optimal dilatation in 49 eyes (32.2%).

The mean preoperative pupillary size was noted to be 6.23 mm (3–7.5 mm), and the mean at the start of the surgery was 6.73 mm (3.5–8 mm) with intracameral adrenaline in all cases. In addition, sphincterotomy was required in 12 cases (7.8%), stretch pupilloplasty in four cases (2.6%), superior iridectomy in two (1.3%), and iris hooks in one (0.7%).

The surgeon faced difficulties during surgery in completing the CCC in 18 cases (11.8%) and in prolapsing the nucleus in seven cases (4.6%), mainly due to the small and rigid pupil. In 14 cases, wrinkling of the anterior capsule during CCC suggested weak zonules.

Among seven intraocular complications, there were five (3.3%) cases of zonular dialysis, three of which had vitreous loss. CTR was placed in all the cases with IOL placement in the bag. There was one case of posterior capsular rupture (PCR) and one case of 1 clock hour iridodialysis.

On postoperative day 1, 18 patients did not have any postoperative complications. The complications are shown in Table 2. While 134 patients had corneal edema of varying degrees, significant edema (pinhole vision 6/18 or less) was seen in 23 (15.1%). Other complications were mild to moderate iritis in 34 patients, fibrinous uveitis in two patients with phacolytic glaucoma, and decentered IOLs in three patients. One patient had central retinal vein occlusion and macular edema.

At 1 week follow-up, 15 patients had DM folds and 10 patients had mild iritis.

Table 1: Sequelae of pseudoexfoliation in the 152 cases included in the study

Sequelae	No. Of Cases	%
Small Pupil	49	32.2
Shallow AC	15	9.9
Phacodonesis	14	9.2
Iris Atrophy	9	5.9
Pupillary Ruff Hypotrophy	9	5.9
Dense PXF	4	2.6
Primary Open Angle Glaucoma/Suspect	2	1.3

Postoperatively at 1 month and 3 months, the corneal complications and iritis had resolved, and irregular pupils due to pupil expanding measures were the most common complication (17 eyes; 11.2%), followed by decentered IOL in three cases (2.0%).

Mean postoperative vision with pinhole on day 1 was 0.26 (±0.24) showing significant improvement in the subsequent follow-up at 1 month and 3 months with the mean best corrected visual acuity (BCVA) being 0.09 (±0.22) ($P < 0.01$) and 0.07 (±0.22) ($P < 0.01$), respectively. The improvement in BCVA in the postoperative period is shown in Table 3.

The mean and range of intraocular pressure during the preoperative period, postoperative 1st week, 1st month, and 3rd month were 14.39 [(±3.4), 8–35], 14.04 [(±2.2), 10–22], 13.37 [(±2.0), 9–22], and 12.53 [(±1.4) 8–16] mm Hg, respectively.

The endothelial cell parameters noted on specular microscopy preoperatively and postoperatively at the first and third months are tabulated in Table 4. There was a statistically significant decrease in the cell density and hexagonality at 1 and 3 months when compared to the preoperative status.

The mean endothelial cell loss was 193.16 (7.79%) at 1 month and 266.01 (10.68%) at 3 months postoperatively.

Discussion

Several studies have reported differences in surgical outcomes between eyes with and without pseudoexfoliation during cataract surgery and have reported an increased risk of complications with all types of cataract surgeries.[5,6,13-16] Our study aims to analyze the outcomes of MSICS in patients with pseudoexfoliation.

Studies have shown that pseudoexfoliation is more common in patients older than 60 years, and the prevalence further increases with age.[3] In our study, the mean age was 67.38 years (± 6.6), and only 12 (7.9%) were below the age of 60. There are conflicting reports about gender predilection. Arvind *et al*.[3] reported that there is no sex predilection, but Avramides *et al*.[15] showed female preponderance. In our study, there were 93 (61.2%) females.

Pseudoexfoliation syndrome has been described to be an asymmetrically bilateral disease by Hammer *et al*.,[17] and 124 patients (81.58%) in our study had bilateral involvement.

As described in the literature, nuclear cataracts are more common with pseudoexfoliation.[3] Our study too had a majority of immature cataracts (88 cases; 57.89%), all of which had nuclear sclerosis grade 2 or 3, and 18 (11.85%) were brunescent cataracts. Preoperative grading of nuclear sclerosis was not possible for 46 mature and hypermature cataracts.

The distribution of pseudoexfoliative material in our cases followed the pattern described in the literature.[1] All our cases (100%) had deposits on the peripheral anterior capsule and the pupillary border.

The sequelae of pseudoexfoliation were also in concurrence with those reported in various studies. Reduction of stromal elasticity by the accumulation of pseudoexfoliation material may play a role in poor mydriasis. In 49 eyes (32.2%) in our study, the pupil size was less than 5 mm after pharmacological dilatation preoperatively. Alfaiate *et al*.[13] noticed significantly

Table 2: Postoperative complications on day 1 and 1 week, 1 month, and 3 months

Complication	Day 1	1 week	1 month	3 months
Corneal complications*	134 (88%)			
Epithelial edema total	34 (22.3%)	0	0	0
Mild Moderate to severe	29 (19.07%) 5 (3.2%)			
Stromal edema total	40 (26.3%)	0	0	0
Mild Moderate to severe	40 (26.3%) 0 (0%)			
Stromal and epithelial edema total	38 (25%)	0	0	0
mild Moderate to severe	20 (13.1%) 18 (11.8%)			
Descemet's folds	22 (14.4%)	15 (9.8%)	0	0
Significant corneal edema**	23 (15.1%)	0	0	0
Iritis (mild to moderate)	34 (22.3%)	10 (6.5%)	0	0
Fibrinous uveitis	2 (1.3%)	0	0	0
Irregular pupil	17 (11.1%)	17 (11.1%)	17 (11.1%)	17 (11.1%)
Decentered IOL	3 (2.0%)	3 (2.0%)	3 (2.0%)	3 (2.0%)
Hyphema	1 (0.7%)	0	0	0

*Includes all grades of epithelial and stromal corneal edema; ** moderate to severe stromal and/or epithelial edema resulting in pinhole vision 6/18 and less

Table 3: Improvement in postoperative best corrected visual acuity from day 1 to 1 week, 1 month, and 3 months

Postoperative Day	6/6-6/9	6/12-6/18	6/24-6/60	<6/60*
Day 1	75 (49.34%)	72 (47.36%)	4 (2.63%)	1 (0.65%)
Day 7	124 (81.57%)	27 (17.76%)	0	1 (0.65%)
1 month	149 (98.02%)	2 (1.31%)	0	1 (0.65%)
3 months	150 (98.68%)	1 (0.65%)	0	1 (0.65%)

*Visual recovery was less than 6/60 due to central retinal vein occlusion with macular edema

Table 4: Comparison of postoperative 1 month and 3 months with preoperative endothelial cell parameters

Parameter	Preoperative Mean (SD) [Range]	1 month Mean (SD) [Range] and *P*	3 months Mean (SD) [Range] and *P*
Cell count	73.70 (±19.7) [32-126]	59.73 (±14.6) [17-109] *P*<0.01	56.99 (±13.9) [28-112] *P*<0.01
Cell Density Cells/mm^2	2446.79 (±401.8) [1127.0-3399.3]	2253.63 (±371.9) [1078.0-3278.6] *P*<0.01	2180.78 (±364.5) [1063.0-3244.0] *P*<0.01
Hexagonality in %	50.26 (±9.1) [25-80]	39.83 (±7.1) [23-57] *P*<0.01	35.59 (±6.6) [21-54] *P*<0.01
Central corneal thickness in microns	492.95 (±38.6) [386-609]	509.81 (±43.0) [407-625]	515.94 (±40.0) [402-617]
Endothelial cell loss mean (percentage)	-	193.16 (7.79%)	266.01 (10.68%)

insufficient mydriasis ($P < 0.001$) in their study. Fourteen (9.2%) patients had weak zonules detected during examination and surgery, while Futa *et al*.[18] and Moreno *et al*.[19] reported a similar incidence of iridophacodonesis in 8.4% and 10.6%, respectively.

Nineteen cases (12.5%) required surgical intervention for small and rigid pupils. Intraoperative management was mainly by sphincterotomy in 12 cases (7.8%), stretch pupilloplasty in four cases (2.6%), superior iridectomy in two (1.3%), and iris hooks in one (0.7%). Alfaiate *et al*.[13] reported that 25.8% of patients required partial sphincterotomies, while Küchle *et al*.[20] noted that 3.4% of their 76 patients undergoing phacoemulsification required mechanical dilatation of the pupil intraoperatively.

In our study, we encountered capsule-related intraocular complications in six cases (4%), of which there were five (3.3%) cases of zonular dialysis and one case (0.7%) of posterior

capsular rupture. In all five cases, CTR was implanted and IOL was placed in the bag, while in the case with PCR, IOL was placed in the sulcus.

Studies have shown a high rate of capsular complications with pseudoexfoliation with the incidence of zonular dehiscence reported as 13.1% by Avramides *et al*.,[15] 14.8% by Lumme *et al*.,[21] and 6.1% in phacoemulsification by Ong *et al*.[22] We also had iridodialysis of 1-clock-hour size in one (0.7%) case, which has also been reported.[14]

Jawad *et al*.[14] (2009) in a series of 200 cases undergoing conventional extracapsular cataract surgery in a teaching hospital reported the following complications: posterior capsule rupture in 9%, vitreous prolapse in 10.5%, retained lens material in 6%, zonular dialysis in 4%, and iridodialysis in 1%.

A more contemporary study by Pranathi *et al*.[16] found poorly dilating pupil in 61.5%, posterior capsule rupture in 7.7%, vitreous loss in 7.7%, retained lens matter in 11.5%, zonular dialysis in 3.8%, and iridodialysis in 1.9% of patients. MSICS or phacoemulsification was performed by a single surgeon in these 52 cases, which is comparable to our study.

The rate of complications in our study was probably less because the surgeries were performed by a single experienced surgeon, and MSICS is a relatively safer technique. However, the complication rate in pseudoexfoliation cases (4%) was at least fourfold more for the surgeon, the rate being < 1% in cases without pseudoexfoliation and other comorbidities.

Mean postoperative vision with pinhole on day 1 was 0.26 (±0.24). The patients showed significant improvement in the subsequent follow-up at 1 month and 3 months with the mean BCVA being 0.09 (±0.22) and 0.07 (±0.22), respectively. On the final follow-up at 3 months, 150 patients (98.68%) had BCVA of 6/6–6/9, and one each (0.7%) had 6/12 and less than 6/60. CRVO is a known complication of pseudoexfoliation[1] and was the cause of vision <6/60 persisting throughout the period of the study.

Epithelial edema due to raised intraocular pressures in 34 (22.3%) patients, Descemet's folds due to prolonged surgical time in 22 (14.4%) patients, stromal edema in 40 (26.3%), and combined epithelial and stroma edema in 38 (25%) especially due to manipulations and shallow AC were the most common complications on the first postoperative day. However, significant corneal edema with pinhole vision 6/18 or less was seen only in 23 (15.1%) The other complications were irregular pupils in 17 cases (11.1%), decentered IOL in three cases (2.0%) iritis in two cases (1.3%), and hyphema in one (0.7%) case.

At 1 month and 3 months postoperatively, the corneal complications had resolved, and the complications that persisted were irregular pupils in 17 and decentered IOL in three eyes.

The intraocular pressure gradually decreased during each visit from the preoperative mean of 14.39 to 12.53 mm Hg at 3 months. None of the cases required antiglaucoma medications beyond 1 week after the resolution of epithelial corneal edema.

In our study, the preoperative mean central corneal thickness (CCT) increased from 492.95 ± 38.6 mm (386–609 mm) to 509.81 ± 43 mm (407–625 mm) and 515.94 ± 40 mm (402–617 mm) at the 1st and 3rd months postoperatively. Similar results were also found by Goldenberg *et al*.,[23] who reported a significant increase in CCT post MSICS in the first postoperative week and first month postoperatively.

A study by Mathew *et al*.[24] showed an increasing trend in CCT after SICS for the first 2 weeks followed by a decrease in the thickness.

Miyake *et al*.[9] and Inoue *et al*.[25] reported lower endothelial cell density in patients with PXF undergoing cataract surgery.

Mean endothelial cell loss noted was 7.79% and 10.68% respectively at 1 and 3 months postoperatively. Kaljurand *et al*.[26] reported a higher loss at 1 month (18.1%) following phacoemulsification in patients with PXF. There was a statistically significant decrease in mean endothelial cell density from 2446.79 (±401.8) cells/mm^2 to 2253.63 (±371.9) at 1 month and 2180.78 (±364.5) cells/mm^2 at 3 months postoperatively ($P < 0.001$). There was also a statistically significant decrease in the mean hexagonality from 50.26% (±9.1) preoperatively to 39.83% (±7.1) and 35.59% (±6.6) at 1 and 3 months, respectively.

Higher complication rates were reported in MSICS compared to phacoemulsification and among trainees compared to consultants in a comparative study by Singh *et al*.[27] Our study shows comparable complication rates and good outcomes, but the limitation is that the surgeries were performed by a single experienced surgeon and there was no comparison with phacoemulsification. The other limitation was a short follow-up period of 3 months owing to patients not complying with a longer follow-up with a dropout rate of more than 20% even at 6 months.

Conclusion

Our study shows that good outcomes can be obtained with MSICS by experienced surgeons in terms of visual recovery and postoperative outcomes. The complication rates may also be comparable to phacoemulsification.

Good postoperative visual outcomes can be achieved with MSICS by careful preoperative evaluation of risk factors and surgical plan, knowledge of and the ability to manage the complications, and timely and adequate surgical modifications such as sphincterotomy depending on the rigidity and level of mydriasis to reduce intraoperative complications.

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Conflicts of interest

There are no conflicts of interest.

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