

Surgical Difficulties and Visual Outcome of Manual Small Incision Cataract Surgery in Patients of Cataract Associated with Pseudoexfoliation Syndrome

Rakesh K. Gupta¹, Rajan Sharma², Ravinder K. Gupta³, Jasdeep Singh Sandhu⁴

ABSTRACT

Introduction: Pseudoexfoliation (PXF) syndrome, first described by John Lindberg, a Finnish ophthalmologist, is an age related fibrilopathy, with manifestations primarily in the eye (1). The changes of exfoliation can be very subtle and can be easily missed in a non-dilated pupil. This study was conducted to evaluate the surgical difficulties and visual outcome of manual small incision cataract surgery in patients of cataract associated with PXF syndrome. Objective: To evaluate the surgical difficulties, post-operative complications and visual outcome of Manual Small Incision Cataract Surgery (MSICS) in patients of cataract associated with Pseudoexfoliation (PXF) syndrome in a teaching institute of north India.

Material and Methods: This prospective cohort study included patients of cataract associated with PXF syndrome scheduled for manual small incision cataract surgery (MSICS) from September 2017 to March 2019. MSICS with posterior chamber intraocular lens implantation was performed and intraoperative difficulties were recorded. Postoperatively, patients were followed-up. The mean IOP pre-operatively and on post-operative day 1 were calculated and compared by Paired T-test.

Results & Conclusion: Forty-three patients were included. The mean age was 67 years (range 51-84 years). PXF material was present on the lens in 11 cases (25.6%), pupillary margin in 10 cases (23.3%) and on the iris in 5 cases (11.6%). Intraoperative difficulties were encountered in 12 patients (28%), the most common problems being poor pupillary dilation (14%) and posterior capsule rupture with or without vitreous disturbance (6.9%). Striate keratopathy at the incision site (23.2%) and irregular pupil due to minisphincterotomies and use of Y-hooks (14%) were the most common complications observed post-operatively. This study highlights the importance of detailed pre-operative evaluation to recognize the presence of PXF material on ocular structures, awareness of complications and ability to manage the complications by modification of intraoperative techniques and regular follow-up of patients undergoing MSICS.

Keywords: Cataract, MSICS, Pseudoexfoliation, Surgical Difficulties, Visual Outcome

INTRODUCTION

Pseudoexfoliation (PXF) syndrome, first described by John Lindberg, a Finnish ophthalmologist, is an age related fibrilopathy, with manifestations primarily in the eye.¹

It is diagnosed by the appearance of grayish white fibrillogranular material (PXF material) on the pupillary margin, anterior surface of lens, iris surface, corneal endothelium and trabecular meshwork.² Appearance of PXF material on the surface of the intraocular lens and on the posterior capsule has been reported, and extracellular material can also be observed in the extra-ocular tissues.^{3,4}

Fibrillogranular material is produced by the epithelial cells in the basement membrane of ciliary body, iris and lens. On histopathology, the deposits are composed of fibrillin, an elastin forming elastic fibers and fibrils, which are non-collagenous basement membrane material. Laminin, glycosaminoglycan and hyaluronic acid coat the fibres and fibrils.⁵ The pathogenesis of PXF is multifactorial including geographical, environmental and genetic factors. PXF is an inherited microfibrilopathy and there is an association with mutations in the Lysyl Oxidase- Like1 gene (LOXL-1) at locus 15q24, which codes for elastic fibre components of extracellular matrix.⁶

The prevalence of PXF shows wide variation worldwide because of various factors like age, ethnic predisposition, geographical location, environmental factors etc. Higher prevalence rates of PXF syndrome have been found in the Northern European, Scandinavian and Mediterranean region.^{7,8} Among the Indian population, the prevalence of PXF syndrome reported in most studies ranges from 0.69-23%.⁹ In a report from southern India, the prevalence of PXF

¹Assistant Professor, Department of Ophthalmology, M.M. Medical College & Hospital, Kumarhatti, Solan, HP, ²Senior Resident, Department of Ophthalmology, M.M. Medical College & Hospital, Kumarhatti, Solan, HP, ³Professor and Head, Department of Ophthalmology, M.M. Medical College & Hospital, Kumarhatti, Solan, HP, ⁴Professor and Head, Department of Physiology, M.M. Medical College & Hospital, Kumarhatti, Solan, HP

Corresponding author: Dr. J.S. Sandhu, Designation: Professor and Head, Department of Physiology, M.M. Medical College & Hospital, Kumarhatti, Solan, HP

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ranged from 3.01% to 6.0% among individuals aged 40 years or more.¹⁰ In a hospital-based study by Joshi RS et al., the reported prevalence in rural central India among patients presenting for cataract surgery was 22.15%.¹¹

PXF syndrome is known to be associated with weak zonules, poor pupillary dilation & hard cataract predisposing the eye to an increased incidence of intraoperative complications like posterior capsule rent, zonular dehiscence, postoperative inflammation and posterior capsule opacification.¹²⁻¹⁴ The changes of exfoliation can be very subtle and can be easily missed in a non-dilated pupil. Hence meticulous examination is very important to diagnose the condition early. A detailed slit lamp examination under high magnification with focal and retroillumination would help pick up early signs of PXF in the anterior lens capsule and pupil. This study was conducted to evaluate the surgical difficulties and visual outcome of manual small incision cataract surgery in patients of cataract associated with PXF syndrome.

MATERIAL AND METHODS

This prospective cohort study was conducted at a medical teaching institute in north India. Patients of cataract associated with PXF syndrome and more than 50 years of age scheduled for manual small incision cataract surgery were included in the study from September 2017 to March 2019. Patients with traumatic cataract, complicated cataract, and PXF glaucoma, IOP>20 mm of Hg, previous ocular surgery and diabetes mellitus were excluded.

The study was approved by the Institutional Ethics Committee and adhered to the tenets of the declaration of Helsinki (1975). Written and informed consents were taken from all patients. The details of the procedure being done including the possible risks and complications were explained to the patients in their language.

The baseline demographic profile of all the study patients was recorded. Detailed history was recorded and best-corrected visual acuity (BCVA) was measured using the Snellen's chart. A complete ocular examination was done which included slit lamp evaluation of the anterior segment. Intraocular pressure (IOP) was measured by non-contact tonometer and the angle of anterior chamber by Goldman four-mirror contact lens. Cataract was graded according to Lens Opacities Classification System 3.¹⁵

All surgeries were preceded by topical Moxifloxacin hydrochloride 0.5% eye drops instilled every 2 hourly 1 day preoperatively, complete asepsis, perioperative conjunctival sac sterilization with povidone-iodine 5%, pupil dilation with Phenylephrine 5% w/v + Tropicamide 0.8%. + Cyclopentolate. Ketorolac 0.5% eye drops were instilled four times at half hour intervals before surgery. Surgeries were performed under peribulbar anesthesia using 2mL of 0.5% bupivacaine and 4 mL of 2% lignocaine mixed with 150 IU of hyaluronidase. Maximum pupil dilation was ascertained and graded as poor (<5mm), fair (5-7mm) and good (7mm or above). Surgeries were performed by two surgeons with more than 15 years of experience in MSICS.

A fornix based conjunctival flap was raised and straight

scleral incision measuring 5.5 mm to 7.0 mm depending on the size and hardness of nucleus, 1 to 1.5 mm behind the limbus made with a 15-no. blade fixed in a bard parker handle followed by sclero-corneal tunnel with a crescent blade. Side port entry was made with 15°-entry blade and trypan blue dye (0.6%) was injected intracamerally under air to stain the anterior capsule. Anterior chamber irrigation was done after 20 seconds to wash out the remaining dye. Hydroxypropyl methylcellulose, a dispersive viscoelastic was injected in the anterior chamber. Continuous curvilinear capsulorrhexis (CCC) aimed at 6mm, was made with 26-gauge needle cystitome. Gentle hydrodissection was done to separate the capsule from corticonuclear mass, followed by prolapse of nucleus in to anterior chamber by Sinsky's hook. Nucleus was delivered outside through the sclerocorneal tunnel by irrigating wire Vectis method. Cortical matter aspiration was done by two-way Simcoe's irrigation and aspiration cannula. The posterior chamber intraocular single piece rigid lens (PMMA) with optic diameter of 6mm was implanted using Kelman McPherson forceps. Viscoelastic material was thoroughly aspirated at the end of surgery, wound was secured and sub-conjunctival gentamycin and dexamethasone 0.5 cc each was injected superiorly.

Modifications in the technique viz. mini sphincterotomies, use of Y-hooks, conversion of CCC to can opener capsulotomy, anterior vitrectomy, implantation of Kelman Multiflex anterior chamber IOL (ACIOL), were made in cases where intraoperative complications were noted. Topical antibiotics (Moxifloxacin) eye drops QID and steroid (Prednisolone Acetate 1%) eye drops 8 times a day, tapered over 4-6 weeks were used post-operatively. Patients were followed-up on the 1st and 7th post-operative day and monthly for the first 3 months. On post-operative visits complete slit lamp evaluation including fundus examination was done and intraocular pressure (IOP) and best-corrected visual acuity were recorded.

STATISTICAL ANALYSES

Descriptive statistics were used to analyze the demographic and clinical characteristics as well as frequencies of intra-operative and post-operative complications. Paired T-test was used to compare the pre-and post-operative IOP and a p-value of ≤ 0.05 was considered as statistically significant. All statistical analyses were performed using the Statistical Package of Social Sciences (SPSS) v23.

RESULTS

Forty-three patients of cataract associated with pseudoexfoliation syndrome planned for MSICS were included in the study. Of these, 25 patients (58.1%) were males and 18 (41.9%) were females. The mean age was 67 years (range 51-84 years) and majority (39.5%) was in the age group of 61 to 70 years. Age and sex-wise distributions has been depicted in table 1. Morphologically, nuclear cataract was the most common type of cataract observed (27.9%) followed by cortical cataract with nuclear sclerosis (20.9%) as shown in table 2.

PXF was seen in both eyes in 22 (61.1%) patients, while 14 (38.9%) had unilateral involvement. 7 patients had pseudophakia and hence laterality was not commented. In the operated eyes, PXF material was present on the lens in 11 (25.6%) cases, on the pupillary margin in 10 (23.3%) cases and on the iris in 5 (11.6%) cases. Both lens and pupillary margin were involved in 7 (16.3%) patients while 10 patients had PXF material on the lens, iris and the pupillary margin. In 2 (4.7%) cases, PXF deposits were seen on endothelial surface of cornea (Table 3).

Pupillary dilation was measured under an operating microscope with a caliper and pupillary dilation <5mm was considered to be a poor pupillary dilation. Pre-operative maximum dilation observed in patients under study was poor in 14% of cases (n=6), fair in 58.1% (n=25) and good in 27.9% (n=12). Maximum pupillary dilation achieved is shown in Table 4.

IOP was recorded pre-operatively and on day 1 and 7 and on post-operative visits at 1 and 3 months. The mean pre-operative IOP was 14.67±2.57 mm Hg while it was significantly higher (16.49 ±2.07 mm Hg) on post-operative day 1 ($p=0.000$). The mean IOP on day 7 was 14.63±0.338 mm Hg. On post-operative visits at 1 and 3 months, mean IOP was 14.56±1.955 and 14.4±2.162 mm Hg respectively. There was no significant difference between pre-operative and post-operative IOP at 1 and 3 months ($p=0.672$ and 0.316, respectively). Preoperative and postoperative IOP values are listed in Table 5.

Intraoperative complications

Of the 43 eyes operated, surgical difficulties were reported in 12 eyes (27.9%). The most common difficulty observed was poor pupillary dilation in 6 eyes (14%), which was managed by mini- sphincterotomies and by use of Y-hooks during the surgery. Continuous curvilinear capsulorrhexis was performed in the studied subjects. Two patients (4.7%) had rhexis extension and were converted to can-opener capsulotomy. A planned can-opener capsulotomy was performed in six patients (14%) with poor pupillary dilation. Two patients (4.7%) had posterior capsular rupture (PCR) without vitreous loss. In the first patient (2.3%) posterior chamber intraocular lens (PCIOL) was implanted in the sulcus while in the second patient, anterior chamber intraocular lens (ACIOL) was implanted after peripheral iridectomy. In one patient (2.3%) with PCR and vitreous loss; anterior vitrectomy was performed and ACIOL was implanted. Of the 2 patients (4.7%) with zonular dialysis, one patient suffered PCR and ACIOL was implanted. Iridodialysis was seen in 1 case (2.3%), which was small and located superiorly and hence left as such covered by the upper lid (Table 6).

Postoperative Complications

Postoperatively, striate keratopathy at the incision site was seen in 10 cases (23.2%). Four patients (9.3%) had corneal edema, which was managed with hypertonic sodium chloride 5% eye drops and resolved on follow-up day 7. Three patients (7%) had signs of significant anterior chamber reaction (+++). A spike in IOP was observed in two cases

(4.7%). Irregular pupil was present in 13.8% cases (n=6) due to syphincterotomy and use of Y-hooks. Hyphema was noted in 2 cases (4.7%), which was minimal and managed conservatively.

Five patients (11.7%) had retained lens matter, of which, 4 (9.4%) had minimal lens matter in subincisional area. In the fifth patient (2.3%), it was noticed in the pupillary area and anterior chamber wash was done on the next day. Two (4.7%) patients developed cystoid macular oedema, which was managed medically. IOL decentration was noted in 1 case (2.3%) at 3 months follow-up.

Visual Outcome

The pre-operative visual acuity ranged from 6/12 to 6/18 in 2.3% cases (n=1), 6/24 to 6/36 in 7% cases (n=3) and 90.7% (n=39) of the patients had preoperative visual acuity less than 6/60. Postoperatively, best-corrected visual acuity (BVCA) attained was between 6/6 to 6/9 in 86% cases (n=37) and between 6/12 to 6/18 in 14% cases (n=6). The pre-operative

Age (Years)	Sex		Number of patients with Pseudoexfoliation
	Males	Females	
51-60	5	5	10 (23.2%)
61-70	9	8	17 (39.5%)
71-80	11	3	14 (32.5%)
81 and above	0	2	2 (4.6%)
Total	25	18	43

Table-1: Age and sex distribution of patients under study

Type of cataract	Number of eyes with PXF (%)
Hyperature	2 (4.7)
Mature	8 (18.6)
Cortical	5 (11.6)
Nuclear Cataract	12 (27.9)
Cortical & nuclear	9 (20.9)
Posterior subcapsular	5 (11.6)
Posterior subcapsular & nuclear	2 (4.7)
Total	43

Table-2: Distribution of morphological type of cataract with PXF

PXF material	Number of eyes (%)
Pupillary Margin	10(23.3)
Iris	5(11.6)
Lens	11(25.6)
Iris, Pupillary margin and lens	10(23.3)
Pupillary margin and Lens	7(16.3)

Table-3: Distribution of PXF in ocular structures

Pupillary Dilation	Number of eyes with PXF (%)
<5mm (poor)	6 (14.0)
5-7mm(fair)	25 (58.1)
>7mm(good)	12 (27.9)

Table-4: Maximum Pupillary Dilation observed

IOP (mm of Hg.)	Pre-operative (%)	Post-operative (%)			
		Day 1	Day 7	1 month	3 months
= < 10	4 (9.3)	0	0	0	1(2.3)
11-15	22(51.2)	13(30.2)	31(72.1)	29(67.4)	31(72.1)
16-20	17(39.5)	28(65.1)	12(27.9)	14(32.6)	11(25.6)
21 & above	0	2(4.7)	0	0	0

Table-5: Pre-operative and postoperative intraocular pressure (IOP)

Surgical difficulties	Number of eyes (%)
Poor pupillary dilation	6 (14%)
Rhexis extension	2 (4.7)
Iridodialysis	1 (2.3)
Zonular dialysis	2 (4.7)
Posterior capsule rupture without vitreous loss	2 (4.7)
Posterior capsule rupture with vitreous Loss	1 (3.4)

Table-6: Surgical difficulties reported

BCVA	Pre-operative	Post-operative			
		Day 1	Day 7	1 month	3 months
6/6- 6/9	0	0	3	24	37 (86.0%)
6/12- 6/18	1	7	29	19	6 (14.0%)
6-24- 6/36	3	24	10	0	0
6/60 & less	39	12	1	0	0

Table-7: Pre- and Post-operative best-corrected visual acuity

and post-operative BCVA is shown in table 7.

DISCUSSION

In this study, we analyzed the demographic and clinical profile of patients with cataract associated with Pseudoexfoliation syndrome. Intra-operative and post-operative complications were evaluated and visual outcomes were recorded.

PXF syndrome is an age-related disorder of extracellular matrix and is characterized by pathologic accumulation of abnormal fibrillar deposits on various ocular structures and extracellular tissues and its incidence increases with age. Patients with age related cataract are elderly and often have coexisting PXF. The age of the patients in our study ranged from 51 to 84 years and majority (39.5%) of them were in the age group of 61 to 70 years. In a study by Joshi RS et al., 26.5% cases were in the age group of 61 to 70 years.¹¹ There is no established sex predilection in patients with PXF. We observed a male preponderance in our study; 58.1% were males and 41.9% were females. This distribution is consistent with the observation of Pranathi et al. who, in their study of 52 patients observed 53.8% males and 46.2% females.¹⁶ However, the Reykavik Eye Study has suggested female predominance among these patients.¹⁷

More than 60% of the patients in our study had bilateral involvement. Most studies have reported a predominantly bilateral involvement with PXF, as the unilateral disease more commonly progresses to a bilateral condition.^{18,19} The intra-ocular distribution of PXF material in our study is consistent with that reported previously. Lens was the most commonly affected (25.6%) followed by the pupillary margin (23.3%) and the pupil, iris and lens together (23.3%).

In a study by Idakwo et al, all patients had PXF material on the peripheral zones of the lens and the pupillary margin.²⁰ Joshi RS et al. reported the distribution of PXF material on the iris, pupil, and lens in 30.9% of the cases in their study.¹¹ Morphologically, nuclear cataract (27.9%) and cortical cataract with nuclear sclerosis (20.9%) were the most common type of cataract observed in the present study. These findings are similar to previously reported studies.^{10,21} An association between PXF and cataract formation appears to exist and nuclear cataract is more frequently found in eyes with PXF than in eyes without PXF.

PXF syndrome is known to be associated with poorly dilating pupils, weak zonules, and hard cataract predisposing the eyes to an increased incidence of PCR or zonular dehiscence. In the present study, intraoperative difficulties were encountered in 28% patients with poor pupillary dilation being the most common problem. Naik & Gadewar have reported intra operative complications in 26% patients during phacoemulsification and 42% patients during MSICS.²² In another study, however, Sastri & Vasavada have reported intra operative difficulties of cataract surgery in PXF eyes being comparable to the non-PXF eyes.²³

Crucial prerequisite for a good surgical outcome in cataract patients is sufficient pupillary dilation throughout surgery and various techniques like viscodilation, mini-sphincterotomies and pupil expansion devices like two-instruments iris stretch with Kuglan or Y-hooks, iris retractors, pupil expansion rings and intracameral injection of lignocaine and epinephrine can be used. In our study, poor pupillary dilation was the most commonly encountered intra-operative difficulty (14%),

which was managed by mini- sphincterotomies or by use of Y-hooks during the surgery. Naik et al., in their study reported 13% cases with poor pupillary dilation²² while Joshi AK et al. reported poor pupillary dilation in 12% of the operated cases, which was managed by sphincterotomies in 24% cases and Y-pushers in 12%.²⁴ In cases with intraoperative miosis, viscomydriasis with high molecular weight cohesive viscoelastic was attempted in our study.

The preferred technique for anterior capsulotomy in MSICS is larger capsulorrhexis measuring about 5.5-6 mm. However, in eyes with PXF, adequately sized and well-centered CCC is challenging in cases with weak zonules as zonular counter traction is compromised. Can-opener capsulotomy is an easier technique to prolapse the nucleus in the anterior chamber especially in cases of large nucleus.²⁵ In our study, planned can-opener capsulotomy was performed in six patients with poor pupillary dilation. Rhexis extension was reported in 2 cases, which were converted to can-opener capsulotomy. Joshi AK et al., in their study managed rhexis extension similarly by converting to can-opener capsulotomy.²⁴

In the present study, posterior capsular rent (PCR) with and without vitreous loss was recorded in two and one case, respectively. Joshi AK et al. in their study reported 8% incidence of PCR, out of which one case was with vitreous loss, which was managed similarly with anterior vitrectomy, peripheral iridotomy and primary ACIOL implantation.²⁴ The overall incidence of PCR reported in the literature varies from 0.2% to 14 %.²⁶

In patients with PXF, Zonular fragility has been associated with increased risk of zonular rupture and vitreous loss. In a study by Lumme et al., eyes with PXF had more intraoperative complications. The vitreous loss was fourfold and there was tenfold AC intraocular lens (ACIOL) placement compared to non-PXF eye.²⁷ In the present study, out of two patients (4.7%) with zonular dialysis, one patient had zonular dialysis with PCR, and ACIOL was implanted. In a study done by Sastry et al., 4 patients had zonular dialysis intraoperatively, out of which 2 cases required scleral-fixated intraocular lens.²³ In our study, iridodialysis was observed in one eye which was small and located superiorly and hence left as such as being covered by upper lid. It is one of the established, although rare complication of cataract surgery. Venkatesh et al., in a study of MSICS in white cataract observed 1% incidence of iridodialysis while Joshi AK et al., observed iridodialysis in 8%.^{23,24}

Cataract surgery has been shown to cause a reduction of IOP months to years after surgery. However, rise in IOP is a known side effect in the early post-operative period, especially within the first 24 hours of surgery. Patients with PXF may have elevated IOP that may be averted by topically pressure-lowering results at the completion of surgery. We observed a significant rise in mean IOP at day 1 post-operatively from baseline IOP, which normalized at day 7 and remained so at 1 and 3 month follow-up. Joshi AK et al. reported no significant difference in the pre and postoperative IOP on day 1, day 7 and 1 month in their

study.²⁴ Sastry et al., in patients with non-glaucomatous PXF noted mean IOP as 26.23 ± 11.40 on 1st postoperative day.²³

Post-operatively, the most common complications noted in our study patients were striate keratopathy at the incision site (23.2%), irregular pupil due to mini sphincterotomies and use of Y-hooks (14%), retained lens matter (11.7%) and corneal oedema (9.3%). Damage to sphincter pupillae was noted in 8% of the patients in a study by Jawad et al. In the same study, decentration of IOL was seen in 4% of the patients and retained lens matter in 6%.²⁸ IOL decentration of the lens was noted in 1 patient in our study at 3 months.

PXF eyes are more prone to develop severe and prolonged inflammation leading to cystoid macular oedema and severe anterior chamber reaction due to alteration of blood-aqueous barrier. In our study, two patients had cystoid macular oedema at 3 months follow-up, which was managed medically. None of the studies have reported CME in operated eyes with PXF. Four patients in our analysis exhibited hypertension, 1 patient had ventricular tachycardia and 1 patient had COPD. Mitchell et al. correlated PXF with increased vascular risk in the Blue Mountain study.²⁹

Quality of vision and early rehabilitation are two of the clinical parameters that determine the success of cataract surgery. Manual small incision cataract surgery offers similar advantages to phacoemulsification due to its less surgical time, low-cost and wider applicability. It is more popular in developing and underdeveloped countries where high volume surgery is the norm. In our study, post-operatively best-corrected visual acuity achieved was between 6/6 to 6/9 in 86% cases and between 6/12 to 6/18 in 14% cases. This is similar to results by Joshi AK et al., where best-corrected visual acuity reported was between 6/6 to 6/12 in 80% of cases and between 6/18 to 6/36 in 20% in patients of cataract with PXF who underwent MSICS.

CONCLUSION

PXF induced iridopathy and phacopathy with zonular instability makes routine cataract surgery a challenging task because of non-dilating pupil, increased risk of zonular dialysis, inadequate size of continuous curvilinear capsulorrhexis (CCC) and associated corneal endothelial dysfunction. Recognition of this condition is hence very important before commencing surgery on such patients and by careful consideration with preoperative preparation; surgical awareness and postoperative follow-up, favorable outcomes can be achieved in cataract surgery. Our study is one of the few prospective studies evaluating the surgical difficulties and post-operative complications with MSICS in this group of patients. This study highlights the importance of detailed pre-operative evaluation to recognize the presence PXF material on ocular structures, awareness of complications and ability to manage the complications by modification of intraoperative techniques and regular follow-up of patients of cataract associated with pseudoexfoliation syndrome. Manual small incision cataract surgery provides a good solution.

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