

Surgical Outcomes of Pseudoexfoliation Syndrome among the Indian Rural Population Scheduled for Small Incision Cataract Surgery: A Prospective Interventional Study

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ABSTRACT

Introduction: Pseudoexfoliation (PXF) syndrome is an age related systemic disorder with primary ocular manifestations characterised by PXF deposits and changes in tissues of anterior segment which make cataract operations potentially challenging.

Aim: To analyse surgical outcomes of Small Incision Cataract Surgery (SICS) on eyes with PXF, compared with eyes without PXF.

Materials and Methods: This prospective interventional study was conducted between August 2015 to June 2016 on each eye of 100 patients who attended free eye camps in rural areas of Western India and underwent SICS. Two groups were formed: group A both males and females of age 50 years or more who had cataract with non glaucomatous PXF (n=50); group B both males and females with age 50 years or more who had cataract without PXF (n=50). Detailed history and slit lamp examinations were done. All the patients were operated upon by the same surgeon. Surgical outcomes assessed were incidence of intraoperative complications, postoperative complications and visual outcomes. Intraoperative difficulties experienced by surgeon like inadequate pupillary dilatation, phacodonesis, zonular dialysis, posterior capsular rupture, vitreous loss etc., were reported. Postoperative findings of

visual acuity, Intraocular Pressure (IOP) and slit lamp evaluation {corneal oedema, anterior chamber inflammation, retained lens matter, hyphema, Intraocular Lens (IOL) centration} on day one and one month were analysed. Comparative analysis of surgical outcomes was done between the two groups by using the Mann-Whitney U test and Fisher's exact test.

Results: The mean age of the patients was 62.48 (± 5.62) years in the PXF group and 60.7 (± 7.63) years in the without PXF group (p=0.1870). Most frequent encountered complication was inadequate pupillary dilatation in PXF group. There was no statistically significant difference in intraoperative complications (zonular dialysis) between the two groups (p=0.4949). Postoperatively, corneal oedema and raised IOP were more in PXF group on postoperative day one compared to group without PXF (p=0.0167, p=0.0226). In both groups, there were no corneal oedema and raised IOP postoperatively at one month follow-up. Both groups had improved visual acuity with no statistical difference at one month follow-up (p=0.5892).

Conclusion: Eyes with PXF undergoing SICS are not associated with a higher rate of surgical complications in our study, however, it requires proper preoperative assessment and intraoperative care to ensure optimal surgical outcomes. In PXF syndrome, more time is required to attain maximal visual acuity in comparison with non PXF patients.

Keywords: Intraoperative complications, Non glaucomatous pseudoexfoliation, Postoperative complications, Visual outcomes

INTRODUCTION

The term PXF was first coined by Lindberg in 1917. Later, in 1925, Vogt described it as a "senile exfoliation". PXF is now recognized as a grey white fibrillary amyloid like material, derived from abnormal extracellular matrix metabolism [1]. The PXF syndrome is an age related systemic disorder with primary ocular manifestations characterised by PXF deposits and changes in the corneal endothelium, pupillary margin of the iris, trabecular meshwork, anterior lens capsule, zonules, ciliary body, and anterior vitreous. PXF deposit has also been reported on IOL and posterior lens capsule [2]. The worldwide prevalence of PXF syndrome has been varied from 0.69-23% [3-15]. Whereas it has been reported between 0.69-3.8% in Indian population [3,4,11,12]. Jonas JB et al., and Stein JD et al., reported it as 0.95% in rural population of central India [4,16].

Alterations of tissues of the anterior segment due to PXF deposit make cataract operations potentially challenging. There are two main pathological manifestations of PXF, zonular weakness and poor pupillary dilatation. Both are most significant risk factors for

intraoperative or postoperative complications. Alterations in tissue might cause intraoperative or postoperative lens dislocation, vitreous loss, capsular phimosis, postoperative prolonged inflammation, postoperative Intraocular Pressure (IOP) spikes leading to glaucomatous disc damage or postoperative corneal decompensation. Scorolli L et al., found that PXF syndrome has a five times greater risk of intraoperative complications during cataract surgery compared with normal cases [17]. Hence, proper preoperative work-up and intraoperative care will reduce the risk of complications during cataract surgery in the PXF syndrome. There is no comparative study which can demonstrate intraoperative, postoperative complications and visual outcomes collectively in patients with and without PXF undergoing cataract surgery. So, the purpose of our study was to compare surgical outcomes (intraoperative, postoperative complications and visual outcomes) among patients with and without PXF undergoing SICS.

MATERIALS AND METHODS

This prospective interventional study was conducted between August 2015 to June 2016 on each eye of 100 patients who attended free

eye camps in rural areas of Western India and underwent cataract surgery- SICS. Approval from the Institutional Ethics Committee was obtained (IEC/17/2015). Written informed consent was obtained from all the patients and the study was conducted in accordance with the tenets of the Declaration of Helsinki.

Sample size calculation: We calculated sample size by comparing proportions of complication rate of surgery in both groups. Power of our study was 0.80. Total sample size was 80 patients (40 patients in each group). By considering dropout rate of 20%, final sample size was 100 patients (50 patients in each group).

Inclusion and Exclusion criteria: Two groups were formed: (a) Both males and females with age 50 years or more who had cataract with non glaucomatous PXF (n=50); (b) Both males and females with age 50 years or more who had cataract without PXF (n=50). These were included in the study. Patients with a history of meiotic use, traumatic cataract, complicated cataract, high myopia, PXF glaucoma and other types of glaucoma, previous ocular surgery, and pre-existing retinal pathology were excluded from both the groups.

Study Procedure

The study sample consisted of each eye of 100 patients. The patients were divided into two groups. Group A included 50 patients with PXF and group B included 50 patients without PXF.

All patients underwent Best-Corrected Visual Acuity (BCVA) test using the Snellen's chart and a complete ocular examination was performed by a trained ophthalmologist by using a slit lamp before and after pupillary dilatation. The amount of pupillary dilatation after instilling mydriatic-cycloplegic (0.8% tropicamide and 5% phenylephrine hydrochloride) drops was noted and recorded as poor (<5 mm), moderate (5-7 mm) or full (>7 mm) dilatation [18]. PXF deposits were looked for on the cornea, pupillary margin of iris and after dilatation- on the anterior lens capsule. The IOP was measured by an applanation tonometer before and after pupillary dilatation. Angle evaluation was done using a Goldmen two mirror gonioscope and was graded by the Shaffer's grading system [19]. Cataract severity was graded using "The Lens Opacity Classification System-III" [20]. A 90D lens and an indirect ophthalmoscope were used to examine the fundus. A B-scan ultrasonography was performed in patients in whom the fundus was not visible. A manual keratometer was used to measure the power of the cornea (keratometry) and A-Scan biometry was used to measure the axial length of the eyeball. The above mentioned parameters were used to calculate the ideal IOL power. The Sanders-Retzlaff-Kraff-II (SRK-II formula) was used to calculate IOL power [21]. Prophylactic ciprofloxacin 0.3% antibiotic eye drops were started one day prior to surgery.

All the patients were operated upon by the same surgeon. All of the operations were performed under the peribulbar block and by using the same technique. A rigid, single piece, biconvex polymethylmethacrylate posterior chamber IOL with an optic diameter of 6.5 mm with dialing holes was used and implanted in the bag/sulcus in all cases. Intraoperative difficulties experienced by surgeon, like inadequate pupillary dilatation, phacodonesis, zonular dialysis, posterior capsular rupture, vitreous loss etc., were reported. Postoperative findings of visual acuity, IOP and slit lamp evaluation (corneal oedema, anterior chamber inflammation, retained lens matter, hyphema) on day one and one month were analysed.

STATISTICAL ANALYSIS

The data was entered into Microsoft Office Excel and analysed by the Epiinfo software 7. Quantitative variables were described using the mean standard deviation after checking the normality of data which was tested using the Kolmogorov test. The Mann-Whitney U test was used to analyse quantitative data. Qualitative variables were described using absolute (N) and relative (%) frequencies. Qualitative data was analysed by Fisher's-exact test. A p-value <0.05 was considered statistically significant.

RESULTS

The mean age of the patients was 62.48 (± 5.62) years in the PXF group and 60.7 (± 7.63) years in the without PXF group ($p=0.1870$). There was no statistically significant difference of IOP between both the groups. There was statistically significant difference of pupillary dilatation between both the groups [Table/Fig-1]. Most common site for PXF deposit in PXF group was anterior lens capsule (n=49) followed by pupillary margin (n=19) and corneal endothelium (n=2). The PXF deposit in PXF group was bilateral in 26 cases, unilateral in 13 cases and laterality could not be commented upon in 11 cases due to pseudophakia in other eye.

Parameters	PXF group (n)	Without PXF group (n)	p-value
Age (Years) (Mean\pmSD)	62.48 \pm 5.62	60.7 \pm 7.63	0.1870
50-60	27	29	
61-70	22	17	
71-80	1	4	
Gender			
Male	29	31	0.8384
Female	21	19	
Visual acuity			
>6/60	27	33	0.3074
\leq 6/60	23	17	
IOP (Mean\pmSD)	15.86 \pm 2.96	14.58 \pm 3.03	0.0587
Pupillary dilation (Mean\pmSD)	6.2 \pm 1.13 mm	8.3 \pm 0.46 mm	0.0001*
Zonular instability	2	0	0.4949
Cataract grading			
<i>Nuclear cataract (grading)</i>			
NC1	1	1	0.9303
NC2	28	31	
NC3	13	12	
NC4	4	2	
NC5	4	4	
Cortical cataract	10	8	0.7953
Posterior subcapsular cataract	16	21	0.4076

[Table/Fig-1]: Demographic and preoperative findings in PXF group and without PXF group.
IOP: Intraocular pressure; Mann-Whitney U test was used; *p-value <0.05 is considered significant

Intraoperative findings are summarised in [Table/Fig-2]. Zonular dialysis was reported in two patients in PXF group who had zonular instability preoperatively.

Clinical features	PXF group n (%)	Without PXF group n (%)	p-value
Inadequate pupillary dilatation	45 (90)	0	<0.001
Posterior capsular rupture	1 (2)	0	1.0000
Phacodonesis	2 (4)	0	0.4949
Zonular dialysis	2 (4)	0	0.4949
Vitreous loss	0	0	-
Sulcus IOL implantation	1 (2)	0	1.0000
Iatrogenic damage to sphincter pupillae	3 (6)	0	0.2424

[Table/Fig-2]: Intraoperative findings in PXF group and without PXF group.
IOL: Intraocular lens; *Fisher's-exact test; p-value <0.05 is considered significant

The postoperative day one findings are summarised in [Table/Fig-3]. There was statistically significant difference in IOP, corneal oedema and visual acuity between the two groups. The postoperative one month findings are summarised in [Table/Fig-4]. No statistically significant differences (visual acuity, IOP, corneal oedema, inflammation) were observed between the two groups. Retained lens matter and hyphema was resolved at one month follow-up in

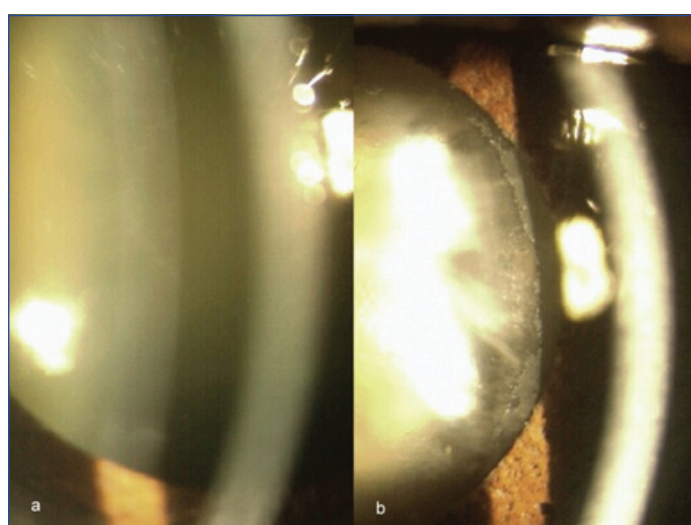
both patients. The [Table/Fig-5] shows central disc of PXF, peripheral granular zone of PXF with well-delineated inner border and outer border extending beneath dilated pupillary margin.

Clinical features (Day 1)	PXF group n (%)	Without PXF group n (%)	p-value
Visual acuity			
≥6/12	34 (68)	46 (92)	0.005*
≤6/18	16 (32)	4 (8)	
IOP >21 mmHg	8 (16)	1 (2)	0.0167*
Corneal oedema	12 (24)	3 (6)	0.0226*
Inflammation (cells >2+)	15 (30)	12 (24)	0.6529
Retained lens matter	0	1 (2)	1.0000
Postoperative hyphema	1 (2)	0	1.0000

[Table/Fig-3]: Postoperative day 1 findings in PXF group and without PXF group. IOP: Intraocular pressure; *Fisher's-exact test; p-value <0.05 is considered significant

Clinical features (1 month)	PXF group n (%)	Without PXF group n (%)	p-value
Visual acuity			
≥6/12	43 (86)	46 (92)	0.5892
≤6/18	7 (14)	4 (8)	
IOP >21 mmHg	0	0	-
Corneal oedema	0	0	-
Inflammation (cells >2+)	1 (2)	0	1.0000
Retained lens matter	0	0	-
Postoperative hyphema	0	0	-

[Table/Fig-4]: Follow-up (at 1 month) findings in PXF and without PXF group. IOP: Intraocular pressure; Fisher's exact test; p-value <0.05 is considered significant

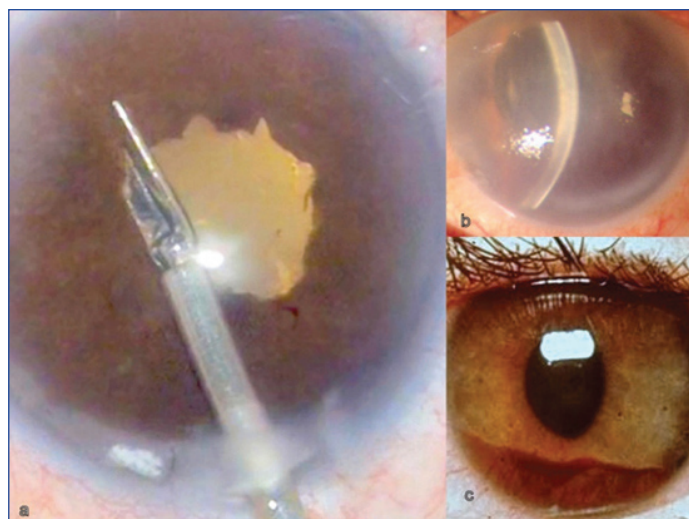


[Table/Fig-5]: Anterior lens capsule a) shows central disc of PXF; b) shows peripheral granular zone of PXF well-delineated delineated inner border and outer border extending beneath dilated pupillary margin.

The [Table/Fig-6] shows sphincterotomy intraoperatively in case with inadequate pupillary dilatation and corneal haze which was noted postoperatively suggestive of corneal oedema along with blood in anterior chamber which was noted postoperatively suggestive of hyphema.

DISCUSSION

This study was performed to compare intraoperative, postoperative complications and visual outcomes between eyes with and without PXF undergoing SICS. There was no statistically significant difference in age between the two groups. The age of patients with PXF in this study was between 50-73 years, which is similar with finding of Jawad M et al., study of PXF syndrome, which demonstrates that it is more common in patients with age more than 60 years [22].



[Table/Fig-6]: Intraoperative and postoperative complications in eyes with PXF. a) Intraoperative sphincterotomy; b) Postoperative corneal oedema; c) Postoperative hyphema.

There was no statistically significant difference in sex between the two groups. However, there were more male patients in both the groups. Male preponderance was reported by Krishnadas R et al., Pranathi K et al., Al-Shaer M et al., Idakwo U et al., who studied PXF in different population which is similar to this study [12,23-25]. Avramides S et al., Kozart DM and Yanoff M, and Arnarsson A et al., reported a female preponderance [26-28]. While Arvind H et al., Jonas JB et al., Miyazaki M et al., Mccarty CA and Taylor HR, You QS et al. and Al-Saleh SA et al., showed no sex predilection [3,4,14, 29-31]. This is because some environmental factors have also been implicated for causing PXF. Male preponderance may be because presentation for cataract surgery is more in the male population than females as seen on comparing with the control group which also has male patients more than female patients.

Most common site for PXF deposit in PXF group is anterior lens capsule (n=49) followed by pupillary margin (n=19) and corneal endothelium (n=2) in this study. It is comparable with studies done by Neelam R et al., and Idakwo U et al., who found anterior lens capsule deposition in all the study participants with PXF syndrome [25,32].

Mean pupillary dilatation was significantly smaller in PXF group as compared to group without PXF. Mean pupillary dilatation in this study was 6.2 ± 1.13 mm in PXF group where as it was 5.40 ± 0.88 mm in Neelam R et al. study and 5.1 ± 1.4 mm in Joshi RS, study [2,32]. The most frequent problem encountered intraoperatively was inadequate pupillary dilatation (≤ 7 mm), which was present in 90% cases of PXF group in this study. Joshi AK et al., Strehlo M et al. and Naik AU and Gadewar SB, found prevalence of inadequate pupillary dilatation in 26%, 88% and 80%, respectively [18,33,34]. We performed sphincterotomy and along with use of cohesive viscoelastic in such cases whenever required. Other alternatives include bimanual stretching, use of iris hooks or flexible iris retractors. We performed iatrogenic sphincterotomy in 6% of cases. In other studies, Jawad M et al., Pranathi K et al., have reported similar incidence rate of iatrogenic sphincterotomy in PXF cases [22,23]. Joshi AK et al. and Srivastava VK et al., also adopted sphincterotomy as commonest measure for nucleus management in PXF cases with inadequate pupillary dilatation [18,35]. Disadvantage of sphincterotomy and bimanual stretching is postoperative distortion of pupil which can lead to the pupillary capture and even glare.

There was no statistically significant difference in preoperative IOP between the two groups which is comparable with study by Neelam R et al., [32]. This might be because we excluded patients with PXF glaucoma and other glaucoma. However, Sufi AR et al., and Shastri L and Vasavada A, report that IOP was significantly higher in patients with PXF [36,37]. There was

statistically significant difference of IOP on postoperative day one between two groups. Eight patients in PXF group and one in group without PXF had an IOP more than 21 mmHg. Naumann GO et al., reports higher IOP in eyes with PXF postoperatively [38]. While lower IOP in PXF group compared to group without PXF after phacoemulsification has been reported by Sufi AR et al., and Shingleton BJ et al., [36,39]. There was no statistically significant difference of IOP at one month follow-up between both the groups.

During preoperative period zonular instability was seen in 4% of patient without vitreous loss. Zonular instability increases the risk of lens dislocation, zonular dialysis or vitreous loss up to 10 times [40]. Jawad M et al., and Pranathi K et al., reported chances of intraoperative zonular dialysis ranged between 4% to 15.6% [22,23]. Whereas Joshi RS reported intraoperative zonular dialysis in 8% of cases [2]. Zonular instability was found in 2(4%) patients preoperatively in this study. Both of them had zonular dialysis intraoperatively. It was less than three clock hours in both cases which did not require capsular tension ring. In both cases IOL were kept in the bag which was stable postoperatively on one month follow-up. There was no vitreous loss in this study. Jawad M et al., Shastri L and Vasavada A and Shingleton BJ et al., report the rate of vitreous loss from 0% to 11% [22,37,39].

There was statistically significant difference for corneal oedema on postoperative day one between both the groups. In present study, 12 (24%) patients had significant corneal oedema in PXF group on postoperative day one, which was resolved on one month follow-up. Pranathi K et al., reported same incidence of corneal oedema postoperatively [23]. The inflammatory cell response was similar in both the groups postoperatively. Similar result was seen in Shingleton BJ et al., study [39]. On the contrary, there was higher incidence of postoperative inflammation in PXF group reported by Neelam R et al., and Sufi AR et al., [32,36].

In comparison of both the groups, there was no statistically significant difference in preoperative visual acuity, but there was statistically significant difference in postoperative day one visual acuity. Visual acuity on postoperative day one was significantly better in without PXF group compared to the group with PXF which is in collaboration with findings of Neelam R et al., study [32]. This might be due to the higher postoperative IOP and corneal oedema which affects the visual acuity in patients with PXF. Corneal oedema may be due to reduced endothelial cell count, increased surgical time and handling in group with PXF. But there was no statistical difference in visual acuity between the two groups at one month follow-up in this study. Shingleton BJ et al., Sarda V et al., Stefan C et al., who conclude that the best visual acuity was similar in both the groups at three month follow up [39,41,42]. Hyphema was observed in one patient of PXF group on postoperative day one in this study, which did not require surgical intervention. The rates of postoperative hyphema have been reported between 1% to 9.4% in other studies [22,23,43].

This study was conducted among cataract patients who visited eye camps at Western part of rural India. We assessed intraoperative, postoperative complications and visual outcomes collectively in with and without PXF cataract patients undergoing SICS. There is no single study which can demonstrate both complications and visual outcomes collectively among such patients.

Limitation(s)

The main limitation of our study was shorter follow-up. Long-term follow-up is needed to comment on glaucomatous disc changes, capsular phimosis and IOL decentration. Furthermore, we did not include pre and postoperative specular microscopy and corneal pachymetry.

CONCLUSION(S)

Proper preoperative assessment and intraoperative care of eyes is required with PXF for safe surgery and good postoperative outcome. Inadequate pupillary dilatation is the most common problem encountered intraoperatively. Conclusively, eyes with PXF undergoing SICS are not associated with a significantly higher rate of surgical complications in our study, however, it requires an optimised surgery.

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