



ORIGINAL RESEARCH PAPER

VISUAL AND SURGICAL OUTCOME IN CATARACT PATIENTS WITH PSEUDOEXFOLIATION FOLLOWING PHACOEMULSIFICATION WITH FOLDABLE INTRAOCULAR LENS IMPLANTATION SURGERY

Ophthalmology

KEY WORDS:

Pseudoexfoliation, Phacoemulsification, Cataract

Dr. Gururaja A N*

Assistant professor, Dept of Ophthalmology, Basaveshwara medical college hospital & research institute, KHB colony, Chitradurga – 577501, Karnataka.
*Corresponding Author

Dr. Revathy KV

Comtrust charitable eye hospital, Thalassery, Kerala.

Dr. Preeti S

Assistant professor, SSIMS&RI, Davangere, Karnataka.

Dr. Aishwarya N

BMCH&RI, Chitradurga, Karnataka.

ABSTRACT

Aim: To evaluate visual and surgical outcome in patients with pseudoexfoliation cataract undergoing phacoemulsification with foldable intra ocular lens implantation surgery. **Methodology:** Hospital based prospective observational study including 100 patients aged above 40 years with cataract and pseudoexfoliation. The parameters like density of cataract, pupillary size, IOP, Visual acuity, Intraoperative behaviour during surgery: zonular weakness, pupillary mydriasis, post-operative complications were noted. All surgeries were done by a single surgeon following phacoemulsification technique. **Results:** The mean age was 62 ± 6 years majority being men. 73 patients had unilateral and 27 had bilateral pseudoexfoliation. Anterior segment examination showed peripupillary deposition of pseudoexfoliation material as most common finding which significantly increased as stage of PXF increased. Grade 3 nuclear cataract was commonly associated with stage 3 PXF. Intra operatively posterior capsular rent in 4 patients and zonular dialysis in 7 patients with hard cataract and stage 3 PXF was noted, which was managed. The visual outcome in all patients was excellent. The mean preoperative vision was 0.71 ± 0.21 (log MAR equivalent) and the postoperative vision at postoperative day 1 was 0.27 ± 0.27 which improved to 0.10 ± 0.14 at the end of third postoperative month with postoperative minimal refractive error of -0.013 ± 0.66 diopters. **Conclusion:** Phacoemulsification is safe and effective procedure in eyes with pseudoexfoliation cataract, when performed by experienced surgeon. Surgeon's expertise for good surgical planning, intra operative use of iris dilating devices, capsule supporting devices, meticulous management of complications is key factor for the good visual outcome.

INTRODUCTION

Pseudoexfoliation is an age related systemic disorder with eye manifestations. It is an abnormal fibrillography characterised by gradual synthesis, accumulation and deposition of fibrillogranular amyloid like exfoliation material throughout the anterior segment of eye⁽¹⁾. It is characterized clinically by small, white deposits of material in the anterior segment, most commonly on the pupillary border and anterior lens capsule. This deposition of material leads to characteristic clinical and ultra-structural changes of lens epithelium/capsule, corneal endothelium, trabecular meshwork, iris, ciliary body, zonules, and structures of blood-aqueous barrier⁽²⁾. The prevalence of pseudoexfoliation increases dramatically with age and is more common in older age groups, with most cases occurring in the late 60s and early 70s⁽³⁾. In a study conducted in South India, it was found that the prevalence of pseudoexfoliation in South India is 3.8 %⁽⁴⁾. Another population based study in South India found out that prevalence is 0.69%⁽⁵⁾. In a study conducted in South India, it was found that the prevalence of pseudoexfoliation in South India have male predominance⁽⁶⁾. The condition may be unilateral or bilateral^(7,8). Patients with bilateral PXF tend to be slightly older than those with unilateral PXF, but the age difference is often small⁽⁹⁾.

Clinical features

The classic pattern consists of three distinct zones that become visible when the pupil is fully dilated. Cataracts occur frequently in eyes with exfoliation syndrome⁽¹⁰⁾. Although this may be in part of the aging process of the patients, cataracts in eyes with exfoliation syndrome have a higher percentage of nuclear opacities and smaller percentage of cortical and sub capsular opacities^(2, 11-12). In patients with uniocular exfoliation syndrome, the involved eye typically has the more advanced cataract. The Reykjavik Eye Study, however, found no association between cataract and exfoliation⁽¹³⁾. Atrophy of the muscle cells may account for the poor mydriasis, which is also a typical finding in the exfoliation syndrome^(2,14). Exfoliation material may be detected earliest on the ciliary processes and zonules.

Deposits of PXF on the zonules may explain the tendency to spontaneous subluxation or dislocation of the lens in advanced cases⁽¹⁵⁾.

Cataract Surgery And Pseudoexfoliation

Nuclear cataract is often more frequently found in eyes with PXF than in eyes without it⁽²⁾. Patients with PXF are much more prone to have complications at the time of cataract extraction. Eyes with PXF dilate less well and have greater incidences of capsular rupture, zonular dehiscence, and vitreous loss. Pupillary diameter and zonular fragility have been suggested as the most important risk factors for capsular rupture and vitreous loss⁽¹⁶⁾. Zonular fragility increases the risk of lens dislocation, zonular dialysis, or vitreous loss up to ten times⁽¹⁾. Inflammation after cataract extraction is more common in eyes with PXF than in those without, and a transitory fibrinoid reaction, attributed to breakdown of the blood aqueous barrier, may occur^(17- 20). Posterior synechiae are more prone to form between the iris and IOL postoperatively^(21, 22). Late postoperative decentration of IOLs and capsular bags was reported to be significantly higher in eyes with PXF and was also related to zonular weakness⁽²³⁾.

Today phacoemulsification has become the norm for routine cataract surgery as a lot of emphasis is laid on early visual rehabilitation. Studies have shown that surgeries done in pseudoexfoliation by experienced surgeons have lower complication rates and excellent visual outcome with careful preoperative evaluation and appropriate intraoperative techniques⁽¹⁸⁾.

There are various studies done to evaluate the effectiveness of phacoemulsification in pseudoexfoliation cataract, but there are very few studies comparing the clinical staging of pseudoexfoliation, pupillary mydriasis and visual outcome in those eyes after phacoemulsification surgery.

Hence we have designed a prospective study to evaluate the visual outcome, intraoperative behaviour of the eyes with cataract and pseudoexfoliation and post-operative

complications following phacoemulsification and intraocular lens implantation surgery.

MATERIAL AND METHODS

Informed consent was obtained from all patients.

1. **Study Site:** Basaveshwara medical college and research institute, Chitradurga, Karnataka, India.

2. **Study Population:** Patients with significant cataract associated with pseudoexfoliation willing to undergo phacoemulsification with intraocular lens implantation.

3. **Study Design:** A hospital based prospective observational study.

4. **Sample Size:** 100 patients (A power analysis using the Gpower computer program indicated that a total sample of 80 would be needed to detect larger effects ($d=.40$) with 80% power using ANOVA among means with $\alpha=.05$)⁽⁶⁰⁾.

5. **DURATION OF STUDY:** Our study was carried out from June 2023 to June 2024

6. **Inclusion Criteria:** Patients greater than 40 years of age with significant cataract associated with pseudoexfoliation who were willing to undergo phacoemulsification with intra ocular lens implantation.

7.Exclusion Criteria

- Patients with lens subluxation >50%.
- Patients with high myopia.
- Patients with traumatic cataract, uveitic cataract, complicated cataract.
- Patients with glaucoma and retinal or neurological pathology that precludes postoperative vision assessment.

METHODOLOGY

Patient information and preliminary symptoms was recorded and detailed examination was carried out.

Parameters studied were

- Clinical profile of patients: laterality; types of cataract; density of cataract; pupillary size evaluation; IOP evaluation; clinical staging of pseudoexfoliation.
- Visual acuity: uncorrected and best corrected visual outcome both pre-operative and post-operative.
- Intraoperative behaviour of the eyes during phacoemulsification surgery: zonular weakness assessment, pupillary mydriasis, anterior chamber stability etc.
- Post-operative complication rates: anterior chamber inflammation, posterior synechia, intraocular lens decentration, postoperative glaucoma etc.

Clinical classification of pseudoexfoliation based on the morphological alteration of anterior capsule⁽¹⁾.

- Pre capsular film (Stage 1)- noted on the anterior capsule which had a ground glass appearance
- Mini exfoliation (Stage 2)-focal defects in the precapsular film that starts nasal-superiorly
- Classical exfoliation (Stage 3)- characteristic appearance of exfoliative material on the anterior capsule with three distinct zones: the three ring sign: a translucent, central disc with curled edges, a clear zone and peripheral granular zone.

Patients were admitted a day prior to surgery after getting clearance for systemic co morbid conditions. Topical antibiotic moxifloxacin drops was applied four times a day.

On the day of surgery, pupil dilatation was achieved using tropicamide 0.8% and phenylephrine 5% along with flurbiprofen 0.03% applied in the conjunctival sac every 15 minutes, one hour prior to surgery.

Peribulbar anaesthesia using 2% lignocaine mixed with hyaluronidase was given to the patient. Surgery was done

under standard asepsis.

Surgical Technique

All surgeries were done by a single senior surgeon. Standard phacoemulsification technique was followed.

Pupillary response after dilatation is measured with Castroviejo callipers and recorded.

Assessment Of Intraoperative Behaviour Of Eye

At the time of surgery, the following intraoperative behaviour of the eye was noted and following supportive measures were carried out;

- For poor pupillary dilatation, intracameral adrenaline or iris hooks, were considered.
- Posterior capsular tear and vitreous loss were managed by automated vitrectomy and intraocular lens implantation either in the sulcus or posterior chamber was done.
- In cases of partial zonular weakness, Morcher® type 14 capsular tension ring was inserted and surgery was performed.

POSTOPERATIVE PERIOD

Pad and bandage was removed on the first post op day. Patients were evaluated for:

Best corrected visual acuity, IOP and, detailed evaluation of anterior chamber was done for corneal edema, hyphema, cells, flares, fibrins, posterior synechia, IOL decentration and subluxation, cortex remnants on post- operative day1, day3, week1, month1 and month3.

Patient was given topical antibiotic-steroid combination drops on tapering schedule. Topical cycloplegic drug was administered in cases with significant anterior chamber reaction.

Patients were assessed for postoperative refraction and corneal astigmatism using automated keratometer on the first and third postoperative month.

Outcome measurement was based on the intraoperative complication rates, postoperative complications at day 1, day 2, week1, month 1 and month3 as assessed with slitlamp, best corrected visual acuity, spherical equivalent and keratometry at postoperative month3.

Statistical Analysis

Data was analysed using professional statistics package EPI Info 7.0 version of windows. Appropriate tests of significance were used depending on the nature and distribution of variables like independent t test for numerical variables and chi square test for categorical variables. One way ANOVA was applied to assess the difference between means in category variable more than two categories.

RESULTS

Demographics:

The age of the patients was in the range of 50-78 years and the maximum number of patients (64) was in the age group of 61-70 years. Pseudoexfoliation with cataract increased as age increased. In our study male patients slightly outnumbered female patients.

Stages Of Pseudoexfoliation:

Clinical classification of pseudoexfoliation based on the morphological alteration of anterior lens capsule was done among these 100 patients. Stage 3 pseudoexfoliation was more commonly seen, followed by stage 2, in our study.

Clinical profile of patients with pseudoexfoliation cataract- stage wise

The age, gender, laterality, preoperative best corrected visual acuity, keratometry, intra ocular pressure and central corneal

thickness of patients were categorized into the 3 stages of pseudoexfoliation and analyzed using one way Anova and Pearson-chi square and were not significant. The fellow eye statuses of these patients were analyzed using Pearsons chi square test and by applying Cochrane rule, p value calculated was not applicable.

Mean keratometry, intra ocular pressure and central corneal thickness of our study participants were within normal limits among the 3 stages of pseudoexfoliation and statistically significant difference was not noted between the stages.

Anterior segment examination of the 100 eyes with pseudoexfoliation showed that loss of pupillary ruff (n=73) and peripupillary pseudoexfoliation material deposition (n=69) were the most consistent pseudoexfoliation related finding. By applying Pearsons-chi square test, these finding, increased with increase in the stage of pseudoexfoliation significantly (p=0.0001). Gonioscopy examination of 100 patients' revealed open angle, of which 9 had pseudoexfoliation material at the angles and 20 had Sampaolesi line in the inferior angle.

The slitlamp examination of 100 patients were analyzed using Pearsons chi square test and by applying Cochrane rule, p value calculated was not applicable for iris transillumination test defect, radial pigment lines over lens capsule, pigments deposition at back of cornea and corneal guttae. Iris transillumination defect was more commonly seen among patients with stage 3 pseudoexfoliation (22%). Eight patients with stage 1 pseudoexfoliation had radial pigment line over the anterior lens capsule, a finding which was present only in one patient in stage 3 pseudoexfoliation. Melanin deposition similar to Krukenberg spindle and corneal guttae was found in a greater number of stage 3 pseudoexfoliation eyes though it was not statistically significant.

The mean intra operative pupil diameter, after maximum mydriasis, among 100 eyes was 5.91 ± 0.63 mm. The pupil diameter between the stages of PXF was found statistically significant by applying one way ANOVA.

Lens opacity classification of cataract grading among 100 patients showed nuclear cataract had the most common association with pseudoexfoliation. Hardness of grade 3 nuclear sclerosis was found in 52% patients.

Intra Operative Procedures And Complications

Out of 100 eyes, adjunctive procedures for pupil dilation were used for 62 eyes [intra cameral adrenaline alone (n=44), iris hook alone (n=9) and intra cameral adrenaline along with iris hook (n=9)]. The supplementary procedures done for pupil mydriasis of these patients were analyzed using Pearsons chi square test and by applying Cochrane rule, p value calculated was not applicable.

Forty nine patients underwent divide and conquer technique and 51 patients underwent phaco chop technique of nucleotomy. Posterior capsular rupture was noted in 4 patients with stage 3 PXF. Automated anterior vitrectomy was done in those patients and 3 piece IOL was implanted either in sulcus or in the posterior chamber. Zonular dehiscence of less than 3 clock hours was noted in 7 patients. Capsular tension ring was inserted in 6 patients. None of the patients required conversion to manual small incision cataract surgery.

The intraoperative complication rate of 100 patients were analyzed stage wise using Pearsons chi square test and by applying Cochrane rule, p value calculated was not applicable.

Postoperative Complications

Early postoperative corneal complication like striate keratopathy and descemet's membrane folds were

statistically greater with higher stage of pseudoexfoliation (Pearson Chi square test). Cornea was clear at the end of third postoperative month, with standard treatment of corneal edema.

Ten cases in stage 3 and stage 2 pseudoexfoliation had descemet's membrane folds in the first postoperative day. Striate keratopathy was seen in 17 cases of stage 3 pseudoexfoliation. On one to one comparison applying post hoc test (bon ferroni comparison) as the stage of pseudoexfoliation increased descemet's membrane folds and striate keratopathy increased significantly.

Early complications like descemet's membrane folds was more common in stage 2 PXF at postoperative day 1 and 3 and in stage 3 PXF at week 1.

Striate keratopathy was most common in stage 3 PXF.

The cornea was clear in the immediate postoperative period in a majority of patients although in all patients cornea cleared subsequently at the end of first month postoperatively.

Severe anterior chamber reaction was considered when the cells $\geq 3+$ and flare $\geq 3+$ by the SUN working group classification of anterior chamber reaction. Thirty one patients in stage 3 PXF had cells more than 3+ on the first postoperative day. Twenty two patients had more than 3+ flare reaction on first postoperative day. By applying Pearson Chi square test, this was statistically significant. On one to one comparison applying post hoc test (bon ferroni comparison) as the stage of pseudoexfoliation increased anterior chamber cells and flare reaction increased significantly.

Other parameters like postoperative posterior chamber intra ocular lens decentration and posterior capsule opacity formation, postoperative pseudoexfoliation material deposition was higher in stage 3 pseudoexfoliation even though it was not statistically significant. Postoperative posterior chamber intra ocular lens decentration was noted in three eyes of stage 3 pseudoexfoliation on the postoperative day 1, day 3, week 1, month 1 and month 3. Posterior capsule opacity formation was seen in 9 eyes of stage 3 pseudoexfoliation on postoperative month 3. By the end of third post-operative month, there was no anterior chamber reaction in any of the stages of pseudoexfoliation.

Anterior chamber cells was reduced by postoperative day 7 in all cases of pseudoexfoliation.

By postoperative month three, anterior chamber flare response was noted in none of the patients we studied.

In our study the mean central corneal thickness was 529.63 ± 16.39 microns. It was found that the mean postoperative central corneal thickness at week 1 was 573.92 ± 19.7 microns, which was greater than the baseline thickness. By third postoperative month, the mean pachymetry was comparable with baseline (530.12 ± 33.65). On applying repeated measure ANOVA it was found to be significant.

In stage 1 and stage 2 pseudoexfoliation, the central corneal thickness reversed to baseline by three month postoperative (stage 1 baseline = 530.19 ± 9.37 , 3 month postoperative = 535.25 ± 8.03 ; stage 2 baseline = 530.23 ± 12.84 , 3 month postoperative = 535.81 ± 15.12) but it remained greater than baseline values in stage 3 PXF (stage 3 baseline = 535.25 ± 8.03 , 3 month postoperative = 541.72 ± 19.86). It was noted that upon one to one comparison between stage 1 and stage 3 pseudoexfoliation at the end of 3rd postoperative month, the central corneal thickness was significantly greater in stage 3 eyes.

The preoperative and postoperative KH and KV values were analyzed using repeated measures anova and were not significant.

The pre-operative and post-operative intraocular pressure was analyzed using repeated measure ANOVA there was significant reduction in intra ocular pressure from the baseline value although the values were within normal limits (15.72 ± 2.62 to 13.18 ± 2.67 , p value = 0.0001).

Upon one to one comparison by post hoc test (bonferroni comparison) we observed a reduction in the postoperative IOP in stage 1 and stage 2 pseudoexfoliation when compared to stage 3 pseudoexfoliation even though it was within normal limits.

Visual outcome in pseudoexfoliation cataract eye following phacoemulsification.

By repeated measure anova, it was found that there was significant improvement in the visual outcome in pseudoexfoliation cataract patients who underwent phacoemulsification. The mean preoperative best corrected visual acuity (log MAR equivalent) was 0.71 ± 0.21 among the 100 eyes studied. The mean post-operative best corrected visual acuity at day 1 was 0.27 ± 0.27 and improved to 0.080 ± 0.13 at the end of 1st post-operative month and 0.10 ± 0.14 at the end of postoperative month 3.

The mean postoperative spherical equivalent was in the range of -0.013 ± 0.66 diopters implying minimal refractive error.

Clinical stages of pseudoexfoliation and pupillary mydriasis

The mean intra operative pupil diameter was 5.91 ± 0.63 millimeters. One to one comparison among the stages of pseudoexfoliation by applying post hoc test (Bonferroni comparison), we found that compared to eyes with stage 1 pseudoexfoliation, the pupil diameter of eyes with stage 3 pseudoexfoliation was significantly smaller ($p = 0.0001$).

Clinical stages of pseudoexfoliation and density of cataract

The 100 eyes of pseudoexfoliation cataract were graded according to the lens opacity classification III. NO3NC3 grade of cataract was seen in 90.56% on stage 3 pseudoexfoliation whereas this was seen only 12.90% on stage 2 pseudoexfoliation eyes. The denser cortical type of cataract also was seen greater in stage 3 PXF (15.09%). Majority of the posterior sub capsular type of cataract was observed in PXF stage 1 but was not significant.

It was noted on applying Kruskal-Wallis test that, as the stage of pseudoexfoliation increased the density of cataract also increased significantly (p value = 0.0001).

Comparison between the clinical stages of pseudoexfoliation with visual outcome

There was no statistically significant difference in the preoperative vision among the three stages of pseudoexfoliation (One way ANOVA). But after phacoemulsification with intraocular lens implantation there was improvement from 0.68 ± 0.21 to 0.04 ± 0.08 in stage one and stage two PXF and 0.71 ± 0.21 to 0.14 ± 0.15 in stage three PXF.

On one to one analysis by Bonferroni test, it was noted that the best corrected visual acuity at postoperative day 1, day 3 and month 3 was significantly less in stage 3 (3rd day 0.25 ± 0.25 , 3rd month 0.14 ± 0.16) compared to stage 1 (3rd day 0.09 ± 0.15 , 3rd month 0.03 ± 0.80)

DISCUSSION

Our study included 100 patients with significant cataract

associated with pseudoexfoliation. These patients were sub grouped into three stages of pseudoexfoliation according to the clinical appearance of the anterior lens capsule on slitlamp biomicroscopy. We noted that the mean age group of the patients were 62.48 ± 6.11 years and there was no gender predilection. Unilateral pseudoexfoliation was more common than bilateral pseudoexfoliation.

Anterior segment examination showed loss of pupillary ruff and peripupillary deposition of pseudoexfoliation material as the most common finding which significantly increased as the stage of PXF increased. Nuclear type of cataract with hardness of grade 3 was commonly associated with stage 3 PXF. The mean intra operative pupil diameter was 5.91 ± 0.63 mm which was significantly smaller in stage 3 PXF (5.46 ± 0.27).

Intra operatively we noted posterior capsular rent in 4 patients and zonular dialysis in 7 patients with hard cataract and stage 3 PXF, which was managed meticulously. No other serious intraoperative complications were noted in our study. Postoperative period was uneventful except for corneal oedema and AC inflammation in patients with stage 3 pseudoexfoliation in the immediate postoperative period that resolved quickly. The intra ocular pressure was within normal limits in all the patients.

The visual outcome in all the patients was excellent. The mean preoperative vision was 0.71 ± 0.21 (log MAR equivalent) and the postoperative vision at postoperative day 1 was 0.27 ± 0.27 which improved to 0.10 ± 0.14 at the end of third postoperative month with postoperative minimal refractive error of -0.013 ± 0.66 diopters.

CONCLUSION

In our study we noted that cataract patients with associated pseudoexfoliation presents with few challenges which was adequately addressed with proper preoperative evaluation, good surgical technique and supportive measures, post-operative care and frequent follow up. Surgeon's expertise for good surgical planning, intra operative usage of supportive measures like iris dilating devices and capsule supporting devices, meticulous management of complications is the key factor for the excellent visual outcome in our study. We conclude that phacoemulsification is safe and effective procedure in eyes with pseudoexfoliation cataract, when performed by experienced surgeon. The overall visual outcome was excellent at end of three month postoperative visit.

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