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Original article

Comparison of incidence of early posterior capsule opacification (PCO) following manual small incision cataract surgery in patients who were implanted rigid PMMA IOL under air, BSS and viscoelastics

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Abstract
Background and Objectives: Comparison of incidence of early posterior capsule opacification (PCO) following manual small incision cataract surgery in patients who were implanted rigid PMMA IOL under air, BSS and viscoelastics. Methods: 219 eyes of patients, divided into three groups of 73 each followed up over the course of 24 months and the incidence of PCO noted at each visit. $P<0.05$ was considered as a statistical level of significance.
Conclusion: The overall incidence of PCO at the end of 24 months study period was 13.6% in our study. No significant statistical difference in the PCO rates among those implanted PMMA IOL under air, saline and visco was observed ($p=0.87$). Minimal cost benefit was afforded for each patient operated under air and BSS than when compared with viscoelastics. Post-operative complications and post op IOP spikes were more to do with the surgeon factor than due to viscoelastics per se ($p>0.05$).

Keywords: PCO, PMMA, air, BSS, viscoelastics

Introduction
Recent day cataract surgery is precision based and moving towards more of a refractive surgery than just cataract extraction and intraocular lens implantation. The expectations of visual rehabilitation post cataract surgery has also drastically increased too. Hence any subnormal vision post cataract surgery is a put off for the patient and the surgeon in equal measure. The causes of subnormal vision post-surgery varies from early causes like surgically induced astigmatism to early development of posterior capsular opacification, which hinders and hampers the quality of life and also increase the cost burden on our patients [1].

PCO-posterior capsular opacification is a post-surgical consequence of any uneventful cataract surgery and is one of the major causes of low visual acuity and low contrast sensitivity [2]. The pathophysiology of posterior capsule opacification involves proliferation, migration and abnormal differentiation of residual lens epithelial cells in the posterior capsule. These lens epithelial cells approach the central visual area in the posterior capsule, resulting in low visual acuity and low contrast sensitivity. Although the duration at which PCO causes low visual acuity following uneventful cataract surgery differs from patient to patient, the mean duration is any time after 6 months of cataract surgery. Multiple factors can have a direct correlation on the incidence rates and severity of PCO, like the surgical technique used, the type and make of IOL & optic-haptic edge designs, retained viscoelastics and finally the surgeon factors [3].

Till the recent past all IOL implantation was done under saline or BSS, but over the course of the years, a safer alternative like viscoelastics are used for IOL implantation. Although viscoelastics has improved a higher rate of safer IOL implantation techniques, it has been observed in previous studies showed an increasing incidence of posterior capsular opacification [3].

Hence, in our current study we studied the delayed incidence of subnormal vision following uneventful cataract surgery due to posterior capsular opacification at our institute when IOL implantation was done under air, BSS and viscoelastics.

Incidence and Prevalence

The incidence of PCO following uneventful cataract surgery was as high as 50% in the early 1990's, although with advent of newer IOL's and improved surgical techniques the incidence had dropped to 17% [4, 5]. The causes and factors affecting early development of PCO include paediatric age, type of cataract (nuclear cataract, PSC, immature cortical cataract), sulcus or in the bag IOL, myopia, secondary surgical intervention, any ocular anomalies, the type, shape, design of the intraocular lens used for implantation, and technique of IOL implantation under air, BSS or viscoelastic [2].

Pathogenesis

The pathogenesis of capsular opacification following cataract surgery results from growth and trans-differentiation of the lens epithelial cells left on the capsule during cataract surgery. Another school of thought found that there is increased expression of smooth muscle isoform of actin, and secrete extracellular matrix containing proteins not normally present in the lens. Whereas, some *in vitro* animal studies observed cytokines like transforming growth factor β (TGF-β) and fibroblast growth factor 2 (FGF-2) act as activators of myofibroblastic differentiation and assist to adhere the LEC's to the posterior capsule [6, 7].

Other factors like Hepatocyte growth factor (HGF), and matrix metalloproteins (MMP) may contribute to the development of PCO. Inhibiting MMP activity can decrease LEC migration and lead to reduction of PCO. Also SPARC protein which inhibits the cell cycle at mid G1 phase may also be a future target for management of PCO [2, 8].

Materials and Methods

The current study was conducted in a tertiary eye care institute in India after due clearance from the institutional ethics committee. This was a retrospective randomised study conducted on 219 eyes conducted on patients who have had manual small incision cataract surgery till December 2018 and followed up over 24 months. The minimum sample size we arrived at by simple random sampling method, considering the previous studies with an incidence rate of 5% was 194 [9]. However we studied 219 eyes. The patients were further divided into three groups comprising of 73 patients each. Group A consisting of 73 patients who were implanted IOL under air, and group B consisting of 73 patients who were implanted IOL under BSS and Group C consisting of 73 patients who were implanted IOL under viscoelastics. All patients were operated by a single surgeon and implanted PMMA PCIOL with square edge haptics under air or BSS or viscoelastics as per the allotted group.

Inclusion criteria

Included all patients with cataract above the 40 years of age, whereas patients with complicated cataracts, patients with long axial length, high myopes, post vitrectomised eyes, IOL power above +25D and below +20D, intraoperative complications like posterior capsular rent or any other eye pathology like glaucoma, retinal disorders were excluded from the study. All patients during their follow-up visits at 1st day post op, 6 months, 12 months, 18 months and at the end of 2 years were examined for visual acuity, iCare tonometry, a dilated examination of fundus and PCO was assessed. PCO assessment was done by Slit lamp biomicroscopy, and its location whether central or peripheral noted.

Primary end point of our study was presence of PCO at the end of 2 years, loss of visual acuity due to PCO, number of patients who needed Nd: YAG capsulotomy for management of PCO. Secondary end points included the comparison of the rate of complications both intra operative and post operatively, visual acuity and post-operative raised IOP between the three groups. *p* value of <0.05 was taken as the level of significance and all the statistical analysis was done by SPSS version 22 software. Chi square and ANOVA was used for assessment where required.

Observation and Results

The patients were followed up over the course of the next 24 months and incidence of PCO if any noted and compared between the three groups. In our study the attrition rate was 6.8% in group A & B, and 8% in group C. The mean age distribution of groups A, B and C were 60.27±7.2, 59±4.01 and 62±5.52 years respectively. The number of male and female patients were comparable in all the groups and exhibited no statistical significance at $P<0.05$ (p 0.386822). The result is not significant at $P<.05$. All the 3 groups were comparable with regards to mean age and sex distribution in our study.

Table 1: Demographic data

Sex	Number	Group A - AIR	Group B - BSS	Group C - VISCO
Mean age in years		60.27±7.2	59±4.01	62±5.52
Male	110	38	40	32
Female	109	35	33	41
Total	219	73	73	73

In our study the overall operating time from start to finish in group A, B & C was 13±1.5 mins, 13±2.03 mins and 14±1.42 mins respectively which was not statistically significant at $P<0.05$. The slight increase in time taken during IOL implantation under visco can be attributed to the time taken for visco wash post-surgery, although not statistically significant.

Table 2: Comparison of the operating time and cost benefit per patient among the three groups

	Group A - Air	Group B - BSS	Group C - Visco
Operated eye			
RE	54% (39)	43% (31)	47% (34)
LE	46% (34)	57% (42)	53% (39)
Operating time in minutes	13±1.5	13±2.03	14±1.42
Cost benefit per patient	+75.00 Rs	+75.00 Rs	-75.00 Rs

On comparison of the post-operative complications observed between the three groups, the most common complications observed were iritis, AC reaction more than2+ to 3+, corneal edema, posterior capsular rent. Group A & C reported a slightly higher incidence of AC reaction 3+/iritis this was probably due to iris touch while IOL implantation and maybe due to occult retained visco in group C. Other complications included corneal edema and posterior capsular rupture the incidence of which was not statistically significant in all the 3 groups. 1st Post-operative day IOP spike was also observed in our study and the difference between the 3 groups were not found to be statistically significant, although a trend towards IOP spike was seen on the first post op day in patients who were implanted PMMA rigid IOL under viscoelastics.

Table 3: Post-operative complications among the three groups

Operative complications	Group A - Air	Group B - Saline	Group C - Visco	*p value* (<0.05)
a) AC rxn, iritis ++ to +++	11	9	14	0.516
b) Corneal edema	4	4	2	0.657
b) PC rent	2	3	3	0.862
c) Post op IOP	12.4±3.2	14.33±2.65	17.03±2.93	

Table 4: Group A - IOL implantation under AIR

Follow up	Number of eyes	V/A	No. of eyes	PCO present
6 month	73	<6/60 6/60-6/18 6/12-6/6	4 8 61	3 (Primary PCO)
12 months	71	<6/60 6/60-6/18 6/12-6/6	5 10 58	4
18 months	68	<6/60 6/60-6/18 6/12-6/6	8 11 54	7
24 months	68	<6/60 6/60-6/18 6/12-6/6	5 14 54	9

Table 5: Group B: IOL implantation under BSS/Saline - followed up over 24 months

Follow up	Number of eyes	V/A	No of eyes	PCO present
6 months	73	<6/60 6/60-6/18 6/12-6/6	4 9 60	4 (Primary PCO)
12 months	70	<6/60 6/60-6/18 6/12-6/6	6 9 54	6
18 months	68	<6/60 6/60-6/18 6/12-6/6	9 9 50	7
24 months	68	<6/60 6/60-6/18 6/12-6/6	11 9 48	10

Table 6: Group C - IOL implantation under viscoelastics - followed up over 24 months

Follow up	Number of eyes	V/A	No of eyes	PCO present
6 month	73	<6/60 6/60-6/18 6/12-6/6	4 7 62	3 (Primary PCO)
12 months	69	<6/60 6/60-6/18 6/12-6/6	4 11 54	5
18 months	67	<6/60 6/60-6/18 6/12-6/6	7 11 49	8
24 months*	67	<6/60 6/60-6/18 6/12-6/6	11 9 47	11

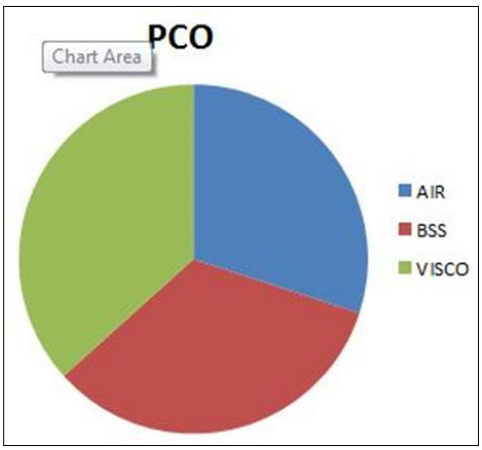

Fig 1: Pie chart representing the % of patients have PCO at the end of 24 months in the three groups. The chi-square statistic is 0.2718. The *p*-value is 0.872909. The result is not significant at *P*<.05

Table 7: Incidence of PCO in different morphological types of cataract (p=0.04)

	PCO in immature cataract	PCO in mature cataract	PCO in PPC
Group A - Air	6	4	0
Group B – BSS	6	3	0
Group C - Visco	7	3	1
Total	19	10	1

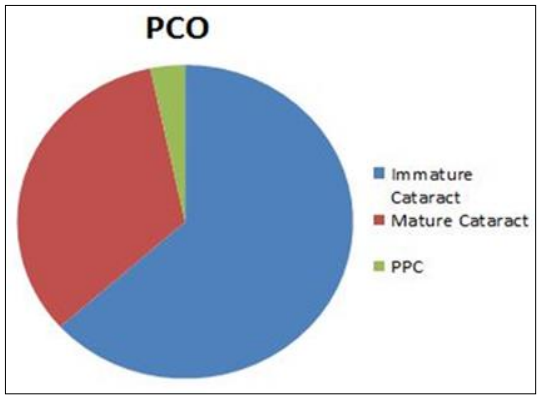

Fig 2: Pie chart representing PCO rates among different morphological types of cataract (p=0.04)

On comparison of the incidence of PCO at the end of 2 years, group C reported 11 cases, whereas group A and B reported 9 and 10 cases respectively. On applying statistical formulae these values were not found to be statistically insignificant. All patients with PCO, with visual deficits during study period were treated with Nd: YAG capsulotomy and improvement noted.

In our study on slit lamp biomicroscopic evaluation for PCO, there was a high prevalence of PCO among immature cataract 8.6% and 4.5% among mature cataract, in whom majority had primary PCO. Central PCO accounted for 23 cases and peripheral PCO accounted for 7 patients.

Discussion

Visually significant PCO is an unavoidable, ill desired consequence of any uneventful cataract surgery occurring in a vast majority of patients at the end of 5 years. The overall incidence of PCO in our study was about 13.6%, which was well in line with that of earlier studies conducted by *Moulick et al*. [4]. On comparison of the incidence of PCO in patients implanted rigid PMMA lens under air, BSS & visco, there was no statistically significant difference between the three groups at the end of 24 months, instead we feel the increased incidence of PCO with visco implantation of IOL observed in studies conducted by *Attarzedeh et al*. [10]. has more to do with inadequate visco-wash and surgeon factor rather than due to use of viscoelastics per se. Our study was a one of a kind study wherein we compared three different methods of IOL implantation, and a direct comparative study similar to our study was lacking. A trend towards a higher incidence of PCO among immature cataracts was noticed when compared with that of mature cataracts which was similar to the study conducted by *Argento et al*. [11]. Nd: YAG capsulotomy was done for all cases with central PCO and were further assessed for visual improvement following the procedure. On comparing the cost benefit afforded to our patients especially in a country like ours wherein the backlog of cataract is multifold, this moderate reduction in the cost observed in group A and group B can go a long way in better allocation of resources in our hospital setup [10]. There was a minimal change in the duration of time taken for completion of surgery, with the extra time afforded in patients who were implanted IOL under viscoelastics, possibly due to time taken for visco wash. The post-operative IOP spikes recorded on the first day did not show any significant statistical difference between the three groups, this finding was seconded by a study conducted by *Ozcura et al*. [12].

Conclusion

Our study findings contradicts the view of earlier studies conducted by *Attarzedeh et al.* [10] who observed an increased incidence of PCO in patients implanted IOL under viscoelastics, which could be due to retained visco or surgeon related factors. Implantation of intraocular lens following cataract extraction under air, BSS or viscoelastics does not increase the incidence of PCO at the end of 24 months of study period, although a longer follow up time and larger population would have been more conducive for the current study. In our study a higher incidence of PCO was observed in patients with immature cataracts, than when compared with mature cataracts. All three methods of IOL implantation were safe and the incidence of complications were not statistically significant between the three groups, albeit it can thus be inferred that the safety profile has got to do more with the surgeon factor than anything else. The increased operative time taken in patients implanted IOL under visco is negligible when compared with other groups.

Lacunae in our study was a lack of data on the CCT and endothelial density, which would have offered more insight into our study.

No financial disclosures.
No conflict of interests.

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