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Original Research Article

VISUAL OUTCOMES AND CLINICAL RESULTS IN DIABETIC PATIENTS WITH FOLDABLE VERSUS RIGID INTRAOCULAR LENSES: A COMPARATIVE STUDY

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ABSTRACT

Background: Diabetes mellitus accelerates cataract progression and predisposes to higher postoperative inflammatory responses, fibrosis and posterior capsular opacification (PCO). IOL biomaterial may influence these outcomes. Foldable acrylic lenses allow smaller incision and lower capsular cell proliferation, whereas rigid PMMA lenses are still widely used in resource-limited settings. Comparative data in diabetics remains clinically relevant. The aim is to compare postoperative visual outcome and clinical results in diabetic patients receiving foldable versus rigid intraocular lenses.
Materials and Methods: This prospective observational comparative study included 100 diabetic patients with senile cataract undergoing SICS, allocated into foldable IOL (n=50) and rigid IOL (n=50) groups. Baseline systemic and ocular parameters were recorded. Postoperative evaluation was performed at Day 1, Week 1, Week 2, Month 2 and Month 6. Primary outcome was BCVA at 6 months; secondary outcome was PCO grading on slit lamp.
Results: At 6 months, 86% (43/50) of foldable IOL patients achieved ≥6/9 vision compared to 58% (29/50) in the rigid IOL group. Early visual recovery was similar at Week 1 and Week 2. Baseline age, sex, PPBS and preoperative VA were comparable across groups. PCO incidence was significantly higher in rigid IOLs by Month 6 (40% moderate–severe vs 10% in foldable group).
Conclusion: Foldable acrylic lenses demonstrated superior long-term visual outcomes and substantially lower PCO compared to rigid lenses in diabetic cataract patients. Lens biomaterial is a critical determinant influencing capsular behaviour, and foldable IOLs should be preferred wherever feasible in diabetic eyes.
Keywords: Cataract, Diabetes Mellitus, Intraocular Lenses, Posterior Capsular Opacification.

INTRODUCTION

Cataract remains the leading reversible cause of blindness worldwide and diabetes mellitus substantially amplifying the risk of progression of cataract formation.[1] Chronic hyperglycaemia promotes cataractogenesis through oxidative stress, activation of the polyol pathway, and osmotic disturbances within the crystalline lens, resulting in earlier cataract development and increased surgical requirements among diabetic patients.[2]
Diabetic individuals demonstrate higher rates of suboptimal postoperative visual recovery due to exaggerated inflammatory responses, impaired wound healing, and increased susceptibility to complications such as macular oedema and posterior capsular opacification (PCO).[3] These factors render intraocular lens (IOL) selection particularly critical in this subgroup, as the implanted lens material and design can significantly influence long-term visual clarity and capsular behaviour.[4]
The transition toward phacoemulsification and small-incision cataract surgery has markedly improved postoperative outcomes, particularly with the use of foldable intraocular lenses.[5] Hydrophobic acrylic foldable IOLs permit implantation through smaller incisions, reduce surgically induced astigmatism, and exhibit

favourable capsular biocompatibility, resulting in lower rates of posterior capsular opacification.[6]

Rigid polymethyl methacrylate (PMMA) lenses, however, continue to have relevance in low-resource environments due to affordability and widespread availability, despite requiring larger incisions and demonstrating higher postoperative inflammation and PCO rates.[7] India, being a high-diabetes-prevalence country where both foldable and rigid IOLs continue to coexist in routine clinical practice, represents an important setting for comparative evaluation.[8]

Given the heightened postoperative vulnerability of diabetic eyes, identifying the IOL category that provides superior functional and structural outcomes is of direct clinical relevance. Contemporary comparative evidence specific to diabetic cataract populations remains limited and variable.[9] Therefore, a direct comparison of foldable versus rigid IOL implantation in diabetic patients is necessary to guide rational IOL selection, particularly in resource-limited surgical settings.[10]

MATERIALS AND METHODS

This prospective observational comparative study was conducted in the Department of Ophthalmology at ASRAM Medical College and Hospital, Eluru, from August 2024 to August 2025. Approval was obtained from the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrolment.

Study Population and Sample Size

A total of 100 eyes of 100 diabetic patients who met the inclusion criteria were enrolled in the study.

Sample Size Calculation

The sample size was calculated using the formula for comparison of two means:

$$n = \frac{2\left(Z_{1-\frac{\alpha}{2}}+Z_{1-\beta}\right)^2 \sigma^2}{(\mu_1-\mu_2)^2}$$

Where:

- $Z_{1-\alpha/2} = 1.96$(for 95% confidence interval)
- $Z_{1-\beta} = 0.84$(for 80% power)
- $\sigma = 0.20$logMAR (pooled standard deviation from previous literature)
- Expected mean difference $(\mu_1 - \mu_2) = 0.10$logMAR

Substituting the values:

$$n = \frac{2(1.96 + 0.84)^2(0.20)^2}{(0.10)^2}$$

= 62.7≈63 subjects per group

Considering feasibility, patient flow, and potential loss to follow-up, a total sample size of 100 eyes was finalized, with 50 eyes in the foldable IOL group and 50 eyes in the rigid IOL group.

Study Period: August 2024 – August 2025 (12 months)

Inclusion Criteria

- Diabetic patients with defective vision due to uncomplicated senile cataract.
- Age 40–70 years.
- Diabetics without retinal changes and PPBS <140 mg/dl.
- Continuous curvilinear capsulorrhexis (CCC) technique used.
- Posterior chamber IOL placement in the capsular bag.
- Minimum follow-up of 6 months.

Exclusion Criteria

- Poor cooperation or inadequate follow-up
- Previous ocular surgery
- History of ocular trauma
- Pre-existing corneal pathology / intraocular inflammation
- Significant posterior segment pathology affecting visual outcome
- Known glaucoma

Methodology

Demographic data including age, sex and refractive status were recorded. A detailed history including presenting complaints, duration of diabetes, systemic conditions, ocular trauma history and prior ocular procedures was taken.

Ophthalmological Examination

- Preoperative unaided and best corrected visual acuity by Snellen's chart
- Slit lamp biomicroscopy including anterior segment and posterior pole evaluation with +90D lens
- IOP measurement by Goldmann applanation tonometry
- A-scan contact biometry, B-scan ultrasonography, keratometry and OCT
- Lacrimal sac syringing for patency
- IOL power calculated using SRK-II formula

Blood Investigations

- FBS
- PPBS
- RBS
- Viral screening
- Blood pressure assessment

Surgical Procedure: All patients underwent manual Small Incision Cataract Surgery (SICS) under aseptic precautions. Peribulbar anaesthesia was given. A sclero-corneal tunnel incision was made and CCC was performed. Hydrodissection and nucleus delivery were carried out using standard SICS technique. Cortical clean-up was done and posterior chamber IOL was implanted in the capsular bag. Depending on group allocation, either foldable IOL or rigid IOL was inserted.

Postoperative Regimen: All patients were prescribed topical antibiotic–steroid combination eyedrops postoperatively with a standard taper protocol as per institutional practice.

Postoperative Evaluation Schedule

- Postoperative Day 1

- Week 1
- Month 1
- Month 3
- Month 6

At every visit, BCVA assessment, slit lamp examination, anterior segment reaction and fundus evaluation were done.

Outcome Measures

Primary Outcome:

- Postoperative Best Corrected Visual Acuity at 6 months.

Secondary Outcome:

- Incidence of Posterior Capsular Opacification (PCO) during follow-up.

PCO assessment was performed subjectively using slit lamp examination and graded as trace, mild, moderate or dense based on capsule clarity and visual axis involvement.

RESULTS

The study population included 100 diabetic patients equally distributed into foldable and rigid IOL groups (50 each). Age distribution showed no statistically significant difference between both groups (p=0.30). Gender distribution was also comparable (p=0.40). Mean PPBS levels were similar in the two groups (119.7 mg/dL vs 120.2 mg/dL), demonstrating uniform glycaemic metabolic status at baseline (p=0.26). Hence, both cohorts were demographically and systemically comparable at entry into the study.

Table 1: Sociodemographic and baseline characteristics (n=100)

Characteristic	Foldable (n=50)	Rigid (n=50)	p value
Age group, n (%)			
40–49 years	20 (40.0)	15 (30.0)	0.30[1]
50–59 years	12 (24.0)	20 (40.0)	
60–69 years	18 (36.0)	15 (30.0)	
Gender, n (%)			
Female	22 (44.0)	31 (62.0)	0.40[1]
Male	28 (56.0)	19 (38.0)	
PPBS, mean (mg/dL)	119.7	120.2	0.26[2]

[1]Chi-square test for distribution across categories. [2]Independent samples t-test. PPBS: post-prandial blood sugar.

Table 2: Baseline (pre-operative) visual acuity (Snellen categories)

VA category (pre-op)	Foldable (n=50)	Rigid (n=50)	p value
≤6/24 (includes CFCF, 4/60, 6/60, 6/36, 6/24), n (%)	30 (60.0)	38 (76.0)	
6/18, n (%)	20 (40.0)	12 (24.0)	0.70[1]

[1]Chi-square test for distribution across categories.

Baseline pre-operative visual acuity status did not differ significantly between the two groups (p=0.70). The majority of patients in both groups presented with moderate-to-severe cataract-related visual impairment (≤6/24 category). This ensures that pre-operative visual function was well balanced between both arms and therefore did not bias postoperative comparisons.

Table 3: Post-operative visual acuity over time (Snellen categories)

Time point	VA category	Foldable (n=50)	Rigid (n=50)	p value
Week 1	≤6/24	10	18	0.09[1]
	6/18–6/12	38	32	
	≥6/9	2	0	
Week 2	≤6/24	13	18	0.50[1]
	6/18–6/12	29	30	
	≥6/9	8	2	
Month 2	≤6/24	2	4	0.04[1]
	6/18–6/12	7	8	
	≥6/9	41	38	
Month 6	≤6/24	3	12	0.02[1]
	6/18–6/12	4	9	
	≥6/9	43	29	

[1]Chi-square test for distribution across categories at each time point.

Visual acuity improved progressively in both groups over time. At Week 1 and Week 2, no statistically significant difference was observed (p=0.09 and p=0.50 respectively), indicating comparable early rehabilitation outcomes. By the 2nd month, a significantly larger proportion of patients in the foldable IOL group achieved VA ≥6/9 (p=0.04). At 6 months, this trend strengthened further, with 86% of the foldable group achieving VA ≥6/9 compared to 58% in the rigid IOL group (p=0.02). Thus, long-term visual outcome favoured foldable IOL implantation.

Table 4: Posterior capsular opacification (PCO) over time and morphology

Time point	PCO grade	Foldable (n=50)	Rigid (n=50)	p value
Week 1	Absent	50	49	0.50[1]
	Grade 1	0	1	
Week 2	Absent	50	48	0.20[1]

	Grade 1	0	1	
	Grade 2	0	1	
Month 2	Absent	48	38	0.02[1]
	Grade 1	2	10	
	Grade 2	0	2	
Month 6	Absent	45	27	0.01[1]
	Grade 1	2	3	
	Grade 2	3	11	
	Grade 3	0	9	

B. PCO morphology at Month 6

Morphology	**Foldable (n=50)**	**Rigid (n=50)**	**p value**
Elschnig's pearls	1	7	—
Fibrous	4	12	—
Mixed (Fibrous + pearls)	0	4	—

Notes: [1]Chi-square test for distribution across grades at each time point. "—" = not evaluated for hypothesis testing in this analysis. PCO grading by slit-lamp (trace/mild/moderate/dense mapped to Grades 1–3).

PCO incidence was minimal and clinically insignificant during the early postoperative period (Week 1 and Week 2, p≥0.20). A statistically significant increase in PCO was observed at Month 2 and was more marked in the rigid IOL group (p=0.02). By Month 6, rigid IOLs demonstrated a substantially higher rate of moderate to dense PCO (p=0.01). Morphologically, fibrous and Elschnig's pearls types were more frequent in the rigid lens group, indicating that lens material characteristics influence the severity and nature of PCO formation over time.

DISCUSSION

The present study evaluated postoperative visual outcomes and posterior capsular behaviour in diabetic patients undergoing cataract surgery with either foldable or rigid intraocular lenses. Although visual rehabilitation improved in both groups, patients receiving foldable IOLs demonstrated significantly superior visual acuity outcomes at intermediate (2-month) and late (6-month) follow-up. This finding highlights the importance of IOL biomaterial and posterior capsular interaction in determining long-term visual performance in diabetic eyes. Similar outcomes have been reported in earlier studies showing that foldable hydrophobic acrylic lenses provide superior effective lens position stability and refractive predictability compared with rigid PMMA lenses.[11,12]

Diabetic eyes exhibit a prolonged postoperative inflammatory response due to chronic low-grade inflammation, increased oxidative stress, basement membrane alterations, and enhanced cytokine expression.[2,3] This altered ocular milieu predisposes to aggressive anterior capsular contraction and posterior capsular epithelial cell migration. Consequently, material-dependent differences in IOL behaviour become clinically magnified in diabetic patients. Hydrophobic acrylic IOLs, owing to their sharp 360° square-edge profile and lower cell adhesion coefficient, effectively inhibit lens epithelial cell migration, whereas PMMA lenses demonstrate a higher fibroproliferative response.[13,14] The findings of the present study are consistent with these observations, as rigid IOLs showed significantly higher PCO grades by Month 6, while foldable acrylic lenses maintained a clearer visual axis.

The divergence in visual outcomes became most evident beyond the second postoperative month. Early postoperative visual acuity at Week 1 and Week 2 was comparable between the two groups, suggesting that immediate postoperative recovery is largely dependent on surgical technique, corneal clarity, and early inflammatory resolution rather than IOL material. This observation concurs with previous reports indicating that material-dependent differences emerge later, once capsular remodelling stabilises and epithelial cell proliferation begins.[15,16]

Posterior capsular opacification was a major differentiating factor between the two cohorts in the present study. PCO developed earlier and progressed more aggressively in the rigid IOL group, with several cases reaching Grade 3 severity by Month 6. In contrast, foldable hydrophobic acrylic lenses demonstrated significantly lower PCO incidence and severity. Similar findings have been reported in multiple studies where PMMA lenses were associated with higher opacification scores and earlier Nd:YAG laser capsulotomy requirements.[17,18] These findings reinforce the concept that optic edge design and biomaterial–capsule interface properties play a decisive role in modulating lens epithelial cell behaviour and capsular fibrosis kinetics.[19-21]

Analysis of PCO morphology further strengthened this interpretation. Fibrous PCO and Elschnig's pearls were predominantly observed in the rigid IOL group. Pearl-type PCO is typically associated with increased epithelial cell proliferation and inadequate barrier effects at the optic edge.[9,22] The predominance of fibrous PCO in diabetic eyes has been reported previously and is believed to reflect underlying metabolic-driven fibroplastic signalling, which rigid lenses are less capable of counteracting effectively.[10,23]

Additionally, superior functional visual outcomes observed in the foldable IOL group may be attributed to improved capsular–IOL conformational alignment. Hydrophobic acrylic lenses maintain closer posterior capsule contact and facilitate formation of a continuous posterior capsular bend, thereby inhibiting epithelial cell migration into the visual axis.[11,15,20] In contrast, rigid PMMA lenses, due to their stiffer geometry and less efficient optic edge design, may fail to maintain this barrier consistently.[11,24]

Overall, this study establishes that in diabetic cataract patients, foldable hydrophobic acrylic IOLs provide superior final best-corrected visual acuity and a significant biological advantage in mitigating posterior capsular opacification. This has important clinical implications in India, where diabetic cataract burden is rising, cataract surgery is increasingly performed at younger ages in diabetics, and IOL selection must balance cost, accessibility, and long-term visual outcomes.[1,8,18] These findings further support the preferential use of foldable acrylic IOLs in diabetic patients wherever feasible.

Limitations

1. The duration of follow-up was restricted to 6 months. Although clinically valid, PCO can continue to develop beyond 1 year in diabetics and longer duration follow-up would provide stronger longitudinal evidence.
2. Only SICS (manual) technique was evaluated and phacoemulsification was not included; therefore cross-platform generalisation cannot be assumed.
3. PCO grading was subjective slit-lamp based method; objective digital EPCO quantification was not performed.
4. Visual acuity was analysed using categorical Snellen bands – logMAR analysis could strengthen statistical resolution in future comparative analyses.

Future Implications

Further research with extended follow-up (>24 months) is recommended to evaluate the long-term behaviour of PCO progression in diabetics. Comparative evaluation between hydrophobic vs hydrophilic foldable lenses and multi-centre RCT designs would allow broader applicability. Incorporation of objective PCO quantification methods (EPCO score / digital retro illumination analysis) and correlation with contrast sensitivity may refine outcome measurement accuracy. Long-term studies may also explore cost-benefit modelling in diabetic cataract populations, considering that rigid PMMA lenses remain in use in resource-limited environments.

CONCLUSION

Foldable acrylic lenses shows superior long-term visual outcomes and significantly lower PCO compared to rigid lenses in diabetic cataract cases. Lens biomaterial is a critical determinant influencing capsular behaviour, and foldable IOLs should be preferred wherever feasible in diabetic eyes. Hence findings of this study supports the preferential use of foldable acrylic IOLs in diabetic patients wherever feasible.

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