Original Article

Comparative Evaluation of Intraocular Pressure Control and Visual Outcomes Following Laser Peripheral Iridotomy versus Early Lens Extraction in Acute Angle- Closure Glaucoma

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Abstract

Background: Primary acute angle-closure glaucoma (AACG) is an eye emergency, as it is a condition when the pressure level in the eye rises sharply because the iridocorneal angle is blocked. The conventional intervention has been laser peripheral iridotomy (LPI), but the recent evidence, among other things, the results of EAGLE trial indicates early planar lens extraction can achieve better long-term results. The objective of the study was to make a comparison of intraocular pressure containment and optical effect after LPI, and early lens removal in patients with primary AACG in Eastern India. **Material and Methods:** This was a prospective observational comparative cohort study that was done at a tertiary care Centre in Kolkata, India. A total of one hundred patients with primary AACG were recruited and randomized to two different groups: LPI (Group A, n=50) or early lens removal in the form of phacoemulsification and intraocular lens implantation (Group B, n=50). Follow-up of patients was done over 12 months. The major outcome was the average IOP decrease after 6 and 12 months. The secondary outcomes were best-corrected visual acuity (BCVA), medication requirement, angle-closure episode recurring, additional intervention requirement, and complications associated with the procedure. Multivariate regression analysis was conducted in order to establish the predictors of IOP reduction. **Results:** There was a similarity on baseline demographic and clinical characteristics ($p>0.05$). The average decrease in IOP at 6 months was much higher in the LE group (18.9 3.8 mmHg) compared to the LPI group (16.4 3.2 mmHg; $p=0.0006$). At 12 months, the difference remained significant (17.6 ± 3.1 mmHg vs. 15.2 ± 3.6 mmHg; $p=0.0005$). A higher proportion of patients in the LE group were medication-free at 12 months (74% vs. 42%; $p=0.0012$). Significant improvement in BCVA was observed only in the LE group ($p<0.001$). The recurrence of angle closure was lower following lens extraction (6% vs. 22%; $p=0.021$). Multivariate analysis identified treatment modality, baseline IOP, anterior chamber depth, and lens thickness as independent predictors of IOP reduction. No sight-threatening complications occurred in either group. **Conclusion:** Early lens extraction provides superior intraocular pressure (IOP) control, greater medication independence, improved visual outcomes, and lower recurrence rates compared to laser peripheral iridotomy in primary acute angle-closure glaucoma. These findings support the consideration of early lens extraction as a preferred first-line intervention in appropriately selected patients. Further multicentre studies with longer follow-up periods are warranted to confirm the long-term benefits.

Keywords: Primary Acute Angle-Closure Glaucoma, Laser Peripheral Iridotomy, Early Lens Extraction, Phacoemulsification, Intraocular Pressure.

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Introduction

Whilst the world health organization acknowledges glaucoma as the leading cause of permanent blindness, its prevalence is expected to increase significantly. Currently, it is estimated that there are 20 million cases attributed to primary angle-closure glaucoma and that the cases will increase to 34 million cases with an additional 5.3m people becoming blind.[1] This burden is disproportionately concentrated in Asia which is thought to have around 60 percent of all glaucoma cases and 76 percent of cases of primary angle-closure glaucoma (PACG) cases worldwide.[2] Primary Acute Angle-Closure Glaucoma (AACG) represents a threatening eye disorder that causes the acute intraocular pressure (IOP) in the eye because of the rapid blockage of the iridocorneal angle. Unattended, it may lead to the irreparable destruction of the optic nerve and irreversible blindness, making AACG one of the minimal ophthalmic crises that require an immediate response to resolve it.[3]

Glaucoma represents the important public health challenge in India. Using pooled data, primary angle-closure glaucoma (PACG) is present in large sub-population of the population, and many of the cases have not been detected since people do not

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have access to eye care services. Population-based research in different areas such as West Bengal has shown that the primary angle closure disease is a high contributor to the total burden of glaucoma, with severe disease and related visual impairment.

Angle closure pathogenesis is characterized by anatomical factors, which include shallow depth of anterior chamber, lens thickening or vault and constricted iridocorneal angle. These cause the pupillary block and the apposition closure of the trabecular meshwork that causes an immediate increase in IOP. Early response is the key to avoiding the loss of optic nerve and disabling vision. Traditional initial management incorporates IOP- reducing medical therapy and then Laser Peripheral Iridotomy (LPI) which opens a second route of aqueous flow through the iris, thus reducing the pupillary block. LPI is however silent on other anatomical factors, including lens induced crowding, and there are patients who are still at risk of developing chronic PACG or have to undergo further procedures to stop the disease.[4]

Although laser peripheral iridotomy has been the most common intervention in the past to relieve pupillary block, recent evidence has indicated that early lens removal (cataract surgery) can provide better control of intraocular pressure and cost-effectiveness in some cases of acute primary angle closure and primary angle closure glaucoma.[5] Various clinical trials have pointed out the possible benefits of lens removal (phacoemulsification) of PACG through deepening of the anterior chamber, broadening the angle of drainage and, consequently, this gives a more definitive anatomical correction. The EAGLE randomised controlled trial (n=12 centres) showed an improvement in the control of IOP, the use of fewer antiglaucomedic drugs, quality of life and cost-effectiveness of early clear lens extraction over the usual care approach employing LPI and antiglaucomedication therapy in patients with PAC and PACG.[6] The fact that new systematic reviews and meta-analyses reinforce the growing role of phacoemulsification in angle-closure disease is not surprising, yet the results of IOP fluctuations between treatment options also differ across studies.

The current debate on whether acute angle- closure glaucoma should be managed with laser peripheral iridotomy (LPI) or early lens extraction urges the need to conduct a deeper researched study as to the relative effectiveness of the two in relation to the various demographical categories.

LPI is not always effective in the treatment of angle-closure disease, depending on the stage of the disease in question.[7] As an illustration, LPI is the appropriate strategy to solve the problem of pupillary block by creating another route to aqueous humours, it need not be entirely anti-angle crowding induced by lenticular action.[8] As a result, the cataract removal can be used as a more effective treatment in cases where the lens makes a significant contribution to the decreasing of the angle and the possibility of unresolved appositional closure after the LPI. This kind of individualistic medicine strategy based on multi-parametric studies of patient parameters is important in identifying the most effective approach of treatment of primary angle-closure disease.[10]

However, as much as LPI is a highly recommended treatment method in the treatment of angle-closure glaucoma, especially in the prevention of the occurrence of primary angle-closure glaucoma (PACG), the role of lens extraction is increasingly becoming crucial in the management of chronic, asymptomatic angle-closure, especially where LPI is found not to effectively open the anterior chamber angle or to where patients need extensive medical care to maintain target intraocular pressure (IOP).The lack of region-specific comparative data is present, however, in part due to the very fact that the region The present local evidence is critical in order to provide management approaches and clinical practice guidelines tailored to acute angle-closure glaucoma (AACG) in Indian contexts.

Hence, this research has been carried out to compare clinical outcomes of LPI and early lens extraction in women with primary acute angle-closure glaucoma in West Bengal, in terms of managing IOP in these patients, dependence of medications, visual acuity, recurrence of angle closure with respect to requirement of further surgical interventions after a period of 12 months.

Materials and Methods

This was a prospective observational comparative cohort study that was carried out in the Ophthalmology Department of Calcutta National Medical College, Kolkata, and West Bengal, India. The research was conducted between May 2023 and November 2023 and another year was allocated to the follow-up and analysis of data. The current study followed the principles of ethics established in the Declaration of Helsinki and adhered to all the relevant institutional and national standards in carrying out the research on human subjects. Before the study started, the subjects received information on specifics of the purpose, the procedures, possible risks, and advantages of the study. Informed consent was collected on the participants through written authority before the enrolment. The target population included patients with what were the diagnoses of the primary acute angle-closure glaucoma (AACG). These patients who approached the Ophthalmology Outpatient Department or Emergency Services of Calcutta National Medical College were included in the study population. They were diagnosed by clinical examination, where there was high-intraocular pressure (IOP), typical anterior segment examination and supportive gonioscopy analysis. They were recruited consecutively according to the predefined inclusion and exclusion criteria. The study's participants were recruited only among new cases who were willing to deliver informed consent. The sample size was predetermined on primary outcome i.e. reduction in mean intraocular pressure (IOP) in the two study groups. The computation was made through analysis of two independent mean when estimates were drawn on the basis of already published literature along with data presented in EAGLE trial. On an assumed clinically significant difference of 3 mmHg in the reduction in IOP between groups with a usual standard deviation of 5 mmHg, two-sided alpha error of 0.05, and 80 percent statistical power gave a calculated sample size of 44 individuals to be included in each group. The sample size was inflated to enrol 50 participants in each group to take care of the expected attrition rate of 10 per cent hence the total number of 100 participants was planned to be enrolled. This

sample size was considered as adequate in order to identify a clinically significant difference and have sufficient power.
Statistical power and statistical precision. This type of study was a prospective form of observational study hence, no randomization was done. Treatment assigning was done depending on clinical evaluation, severity of the disease, anatomy as well as preference by the treating consultant (BB). The patients who had laser peripheral iridotomy were Group A and early lens extraction through phacoemulsification and intraocular lens implantation comprised Group B. These two procedures were done as normal clinical practices. Since the treatment assignment was not random, the selection bias was minimized by recruiting eligible patients in sequence and using the same selection and exclusion criteria in both groups. Baseline demographic and clinical background was recorded in order to make relevant comparative analysis and correct some possible confounders, where they were required.

Inclusion Criteria
Age ≥ 40 years
Diagnosed cases of Primary Acute Angle-Closure Glaucoma
Resolution of acute attack after initial medical management
Willingness to provide informed consent

Exclusion Criteria
Secondary angle-closure glaucoma Previous intraocular surgery
Advanced glaucomatous optic neuropathy Corneal opacity preventing adequate assessment Patients unwilling for follow-up

All patients who were eligible were subjected to a full ophthalmic examination at presentation. A thorough clinical history was ascertained including the advent of the symptoms, the safe period of the acute attack, previous eye history, and comorbid disease. The visual acuity with the help of Snellen chart with best-corrected visual acuity assessed was measured as standardized. The slit-lamp biomicroscopy was used to examine the anterior segment. Goldmann applanation tonometry was used to measure intraocular pressure (IOP). A standardized grading system was used to conduct angle assessment using gonioscopy. Where possible, posteriors segment testing, including an examination of the optic disc was done with slit-lamp biomicroscopy through the use of a fundus lens to ensure pupil expansion. Anterior chamber geometry and angle position was recorded using anterior segment optical coherence tomography (AS-OCT).
After the preliminary medical treatment to stabilize intraocular pressure and the acute attack, definite treatment took place. The patients received either laser peripheral iridotomy or early lens removal with phacoemulsification and intraocular lens implantation, according to the normal practice in the institution.
A prospective follow-up of all the participants was carried out at set intervals of 1 week, 1 month, 3 months, 6 months and 12 months after definitive treatment. A standardized ophthalmic examination was conducted in every follow-up visit. Goldmann applanation tonometry was used in the measurement of intraocular pressure (IOP) and the best-corrected visual acuity (BCVA) was checked with the help of a Snellen chart. Gonioscopy was used to get the status of anterior chamber angle. The complications during the operation or even after it were properly recorded. Moreover, the count and category of antiglaucoma medicines, which were to be used during every visit, were addressed.
Adherence was further motivated by the follow-up when the patient received a reminder of the appointment so as to entertain minimal turnover and proper completion of the outcome measurement.
The base of the intraocular pressure (IOP) was the primary outcome measure at the baseline, 6 and 12 months after the definitive treatment. The applanation tonometry (Goldmann) on IOP measurements were taken, and average change of baseline was calculated on every group.
The outcome measures that were used secondarily were:
Antiglaucoma drugs needed at each follow-up attendance.
Best-corrected visual acuity (BCVA) with the help of a normalized Snellen chart.
Extent of widening of angles as determined by gonioscopy and /or anterior segment optical coherence tomography (AS-OCT) when available.
Angel nature angle-closure recurrence in the follow up period Prerequisite to further surgical/laser resection Requirement of complications involving the procedures
The results were measured at specific intervals of follow-up to maintain consistency in the data collection process and to allow comparing the results of both groups. Any data were captured in a designed and standardized pro forma, which then were inputted in the Microsoft Excel (Microsoft Corp., Redmond, WA, USA) to manage the data. Each participant was given a special identification number in order to protect the confidentiality, and the personal identification information was deleted before conducting the analysis.
Statistical analyses were conducted using GraphPad Prism (version 10.6.1) and IBM SPSS Statistics (version 31). Continuous variables are expressed as mean ± standard deviation (SD), whereas categorical variables are expressed as frequencies and percentages. For inferential analysis, the independent samples t-test was used to compare the mean reduction in intraocular pressure (IOP) between the two groups. The chi-squared test was used to compare categorical variables. A two-tailed p-value of < 0.05 was considered statistically significant.

Results

A total of 100 patients diagnosed with Primary Acute Angle-Closure Glaucoma were included in the study. Fifty patients underwent Laser Peripheral Iridotomy (LPI) (Group A), and fifty patients underwent Early Lens Extraction (Group B). All patients completed 12 months of follow-up.
The mean age of participants was 57.6 ± 8.4 years in Group A and 58.2 ± 7.9 years in Group B ($p = 0.71$). Females constituted 66 % of study population in group A and 70% of study population in group B. Baseline demographic and clinical parameters were comparable between the two groups [Table 1].

Table 1: Baseline Demographic and Clinical Characteristics

Variable	LPI Group (n=50)	Lens Extraction Group (n=50)	p-value
Mean Age (years)	57.6 ± 8.4	58.2 ± 7.9	0.71
Female, n (%)	33 (66%)	35 (70%)	0.67
Baseline IOP (mmHg)	33.3 ± 6.5	34.7 ± 6.9	0.30
BCVA (logMAR)	0.46 ± 0.21	0.49 ± 0.24	0.51
Anterior Chamber Depth (mm)	2.20 ± 0.24	2.12 ± 0.26	0.11

There was no statistically significant difference between groups at baseline.

At 6 months, the mean IOP reduction was significantly greater in the Early Lens Extraction group (18.9 ± 3.8 mmHg) compared to the LPI group (16.4 ± 3.2 mmHg) (p = 0.0006).

At 12 months, the difference remained statistically significant, with mean IOP reduction of 17.6 ± 3.1 mmHg in the Lens Extraction group compared to 15.2 ± 3.6 mmHg in the LPI group (p = 0.0005) [Table 2].

Table 2: Comparison of Mean IOP Reduction

Follow-Up	LPI Group (n=50)	Lens Extraction Group (n=50)	p-value
6 Months	16.4 ± 3.2 mmHg	18.9 ± 3.8 mmHg	0.0006*
12 Months	15.2 ± 3.6 mmHg	17.6 ± 3.1 mmHg	0.0005*
Significant			

At 12 months follow-up, a significantly higher proportion of patients in the LPI group required at least one antiglaucoma medication compared to the Lens Extraction group (58% vs. 26%, p = 0.001). Conversely, a greater proportion of patients in the Lens Extraction group were medication-free at 12 months (74% vs. 42%). This finding indicates that early lens extraction provides superior long-term intraocular pressure control and reduces the need for ongoing topical antiglaucoma therapy compared to laser peripheral iridotomy. [Table 3].

Table 3: Post-Treatment Medication Requirement at 12 Months

Medication Requirement	LPI Group (n=50)	Lens Extraction Group (n=50)	p-value
No medication	21 (42%)	37 (74%)	
≥1 medication	29 (58%)	13 (26%)	0.0012

At 12 months, the Lens Extraction group demonstrated a significant improvement in best- corrected visual acuity (BCVA), with mean logMAR values improving from 0.50 ± 0.24 at baseline to 0.18 ± 0.12 (p < 0.001). In contrast, the LPI group showed no statistically significant change in BCVA (0.48 ± 0.21 to 0.44 ± 0.18; p = 0.12). Between-group comparison at 12 months revealed significantly better visual outcomes in the Lens Extraction group compared to the LPI group (p < 0.001), highlighting the functional advantage of early lens extraction in patients with primary acute angle-closure glaucoma.

At 12 months, recurrent angle-closure episodes occurred in 11 patients (22%) in the LPI group compared to 3 patients (6%) in the Lens Extraction group. This difference was statistically significant (p = 0.021), indicating that early lens extraction was associated with a markedly lower risk of recurrence. These findings underscore the long-term anatomic and functional advantages of lens extraction over laser peripheral iridotomy in patients with primary acute angle-closure glaucoma.

Mild transient anterior chamber inflammation was more common in the Lens Extraction group (20%) compared to the LPI group (8%). However, no sight-threatening complications were observed in either group.

Multivariate linear regression analysis was performed to identify independent predictors of 12-month intraocular pressure (IOP) reduction [Table 4]. Treatment type emerged as a significant independent predictor, with early lens extraction associated with a 3.2 mmHg greater reduction in IOP compared to LPI after adjusting for potential confounders (95% CI: 1.4–5.0; p = 0.001). Higher baseline IOP was also a significant predictor of greater absolute IOP reduction (β = 0.42 mmHg per mmHg increase; 95% CI: 0.25–0.59; p < 0.001). Anatomical parameters including shallower anterior chamber depth (β = 1.8; 95% CI: 0.5–3.1; p = 0.007) and thicker lens (β = -1.5; 95% CI: -2.6 to -0.4; p = 0.008) were independently associated with a better response to lens extraction. In contrast, age (p = 0.41) and sex (p = 0.38) were not significant predictors of IOP reduction in this cohort. These findings highlight the importance of baseline ocular anatomy and treatment modality in determining long-term pressure-lowering outcomes in primary acute angle-closure glaucoma.

Table 4: Multivariate Linear Regression for Predictors of 12-Month IOP Reduction

Predictor	β Coefficient (mmHg)	95% CI	p-value
Treatment (Lens Extraction vs LPI)	3.2	1.4 – 5.0	0.001
Age (per year increase)	-0.05	-0.17 – 0.07	0.41
Baseline IOP (per mmHg increase)	0.42	0.25 – 0.59	<0.001
Anterior Chamber Depth (mm)	1.8	0.5 – 3.1	0.007
Lens Thickness (mm)	-1.5	-2.6 – -0.4	0.008
Female Sex (vs Male)	0.6	-0.8 – 2.0	0.38

Discussion

This prospective comparative study assessed intraocular pressure (IOP) control, visual outcomes, and medication dependence in patients with primary acute angle-closure glaucoma (PACG) undergoing laser peripheral iridotomy (LPI) versus early lens extraction (ELE). Our findings indicate that early lens extraction provides superior anatomical, functional, and long- term IOP-lowering outcomes compared to LPI, corroborating recent high-quality evidence.

In our cohort, the mean IOP reduction at 12 months was significantly greater in the ELE group (17.6 ± 3.1 mmHg) compared to the LPI group (15.2 ± 3.6 mmHg, p = 0.0005). Furthermore, 74% of patients in the ELE group were medication-free at 12 months, compared to 42% in the LPI group (p = 0.001). These findings are consistent with previous studies demonstrating the superior pressure-lowering effect of lens extraction in both acute and chronic angle-closure glaucoma. The EAGLE trial, a multicenter randomized controlled trial, reported similar results, showing that early lens extraction was more effective than LPI in lowering IOP and reducing the need for medications in PACG.[13] Similarly, the Cochrane review by Pose-Bazarra and Azuara-Blanco concluded that early lens extraction may provide better IOP control compared to LPI in acute angle-closure, albeit based on low-certainty evidence from two studies.[6,14] In addition to the IOP decrease, there was a considerable increase in the level of best-corrected visual acuity (BCVA), which was enhanced after therapy (program, 0.50 on average and variance of 0.24), and after 12 months (0.18, on average and variance of 0.12). LPI, on the contrary, did not generate statistically significant changes. Lens extraction deals with the lens-induced.

Part of the angle crowding and can treat other cataracts occurring in the same eye, therefore enhancing anatomical arrangement and vision. Such findings are consistent with the findings reported by Pose-Bazarra et al., who found superior clinical and quality-of-life outcomes after clear lens removal as compared to LPI in early- or moderate-PACG.[6,14] A greater number of repeated angle-closure events were observed among patients against the LPI group (22 per cent) compared to the ELE group (6 per cent) (p = 0.021). This disparity probably represents the mechanistic benefit of lens extraction, which increases the depth of anterior chamber, and expands the angle and eliminates the lens-imposed pupillary block. The same case was reported by Chenxi Yan et al., who found more profound anterior chambers, with broader angles following the removal of the lens, which improved the stability in relation to IOP on a long term basis.[15] These anatomical alterations have the benefit of making recurrence less likely, but LPI treats the pupillary block only and does not necessarily change the pupillary lens-caused angle crowding.

The results of the multivariate analysis of our research showed that the independent factors predicting a decrease in the IOP were treatment modality, baseline IOP, anterior chamber depth, and lens thickness. There was no significant age and sex, as was described previously.[16] These results highlight the role of ocular anatomy in identifying the response to treatment, which supports the idea of a personal approach to the intervention of PACG.

Even though mild transient anterior chamber inflammation was more common after lens extraction (20% vs. 8%), no complications that may pose a threat to sight were documented. These results are in line with the available literature, which routinely reveals low mortality rates of grave unfavorable incidents that are linked to modern phacoemulsification methods.[13]

In combination with the existing literature, our results recommend high consideration in the early lens extraction as a primary treatment option in the acute forms of angle-closure glaucoma patients especially those with shallow anterior chambers, thick lenses or even visually important concomitant cataracts. Acute Laser peripheral iridotomy (LPI) can be a good option managing intraocular pressure (IOP) in patients unsuitable to have surgery or in the meantime; though its long term effectiveness does not seem to have been well reported, and a high percentage of patients ultimately need lens removal.[17]

The strengths of this study are as follows: the study was prospectively designed, had standardized follow-up, and evaluates anatomical and functional outcomes completely. Our study has the weakness of single-centre recruitment, a relatively small size of a sample, as well as the use of the rather limited follow- up of 12 months. Multicentre studies, which would allow evaluation of the long-term IOP control, quality-of-life, and visual outcomes, are required. Ahead of Lens excision offers great IOP management, decrease in medication reliance, better optical results, and a lower recurrence of episodes of angle-closure than LPI in acute angle-closure glaucoma. These results justify a change in mindset towards lens removal as a primary procedure, especially in eyes with an anatomical predisposition, and the need to take the eye structure into account when choosing a treatment procedure.

Conclusion

Early lens extraction had better clinical outcomes than laser peripheral iridotomy in this prospective comparative study of patients with primary acute angle- closure glaucoma. The reduction of intraocular pressure by the use of lenses was far better at 6 and 12 months, fewer antiglaucomed usage, and an overall better or enhanced correction of visual acuity, and occurrence rate of angle- closure events was low in patients undergoing lens extraction.

This was based on multivariate analysis that treatment modality and baseline intraocular pressure, anterior chamber depth, and lens thickness were predictors of long-term intraocular pressure reduction with the significance of anatomical consideration as the foundation of therapeutic choice. Despite the fact that mild transient inflammation of the anterior chamber was more common after, lens extraction, there were no sight-threatening complications detected, which seems to argue in favor of the general safety of the practice under the conditions of suitable choice.

Strengths: There are a number of strengths of this study. It used a prospective design that used standardized follow-up after 12 months and obtained 100 percent follow-up of all the enrolled

participants. There was similarity in the baseline features of the groups, which minimized confounding. Multivariate regression analysis and thorough evaluation based on anatomical, functional, and clinical outcome measures, was conducted to find out independent predictors of intraocular pressure lowering. Also, the study has valuable region specific data in Eastern India where little comparative evidence is represented.

Limitations

There are some drawbacks that should be admitted. It was conducted in one tertiary-care centre and hence this might be limiting in the generalization. The allocation of treatment was non-random, and it was dependent on clinical judgment and patient preference, which could cause selection bias. The size of the sample, though large enough to produce primary outcomes, is rather small. The 12-month follow-up period might not comprehensively respond to the long-term disease development, complications or permanent medication non-dependence. Also, the quality-of-life measurement and cost-effectiveness were not assessed with the formal criteria.

Future Recommendations

To confirm these findings, future studies must involve multicentre randomized controlled trials and a higher sample size and increased follow-up periods. Research that includes patient-reported outcome, quality-of-life measurements, and cost-effectiveness would give a more thorough analysis of impact of treatment. Further stratification of anatomical risk factors by advanced imaging can further improve patient selection and promote a personalized treatment approach. To ascertain the long-term features of early lens extraction with regard to providing sustained safeguard against the chronic evolution of angle-closure glaucoma, long-term data will prove to be crucial.

Conclusively, early lens excision is superior to laser peripheral iridotomy, in glaucoma in the primary instances of acute angle-closure. These results justify further discussion of lens extraction as a first-choice treatment in a carefully selected group of patients, those with angle crowding as a result of lens usage, and shallow anterior chambers.

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Conflicts of interest

There are no conflicts of interest.

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