DOI: 10.7860/JCDR/2026/78351.22285

Research Protocol

Ophthalmology Section

Evaluating Predictors of Outcomes and Safety of Various Cataract Surgery Techniques in Eyes with Coloboma: A Research Protocol

ASHISH SHARMA[1], SHASHANK BANAIT[2]

ABSTRACT

Introduction: Coloboma, a congenital defect resulting from the incomplete closure of the embryonal fissure, often affects the inferonasal part of the fundus. It is frequently associated with cataracts, which are a leading treatable cause of visual impairment. However, cataract surgery in colobomatous eyes presents significant challenges due to anatomical anomalies such as microcornea, zonular instability, poor pupillary dilation and structural irregularities.

Need of the study: Cataract development is common in eyes with coloboma and significantly impacts vision, causing blurry vision, glare sensitivity and difficulties with daily activities. Cataract surgery in these eyes poses unique challenges due to the underlying anatomical abnormalities. Understanding the predictors of outcomes and the safety of different surgical techniques is crucial for optimising care and improving visual outcomes for patients with coloboma. By identifying factors associated with better or worse results, surgeons can tailor their approach to each individual patient, reducing risks and enhancing the chances of successful visual rehabilitation.

Aim: The aim of this study is to evaluate different cataract surgeries for eyes with colobomas, as well as the safety and outcome predictors of various surgical methods.

Materials and Methods: This hospital-based prospective interventional study will be conducted at the Department of Ophthalmology, Acharya Vinobha Bhave Rural Hospital, Sawangi, Maharashtra, India, over two years (May 2024 - April 2026) with 34 patients. The study aims to evaluate the outcomes and safety of cataract surgery techniques, including Phacoemulsification (PE) and Manual Small Incision Cataract Surgery (M-SICS). The type of surgery will depend on the degree of microcornea, cataract hardness and zonular stability. Preoperative, intraoperative and postoperative assessments will include detailed ophthalmic evaluations, visual acuity measurements, grading of microcornea and monitoring for complications such as corneal edema, using standardised grading systems. Statistical analysis will be performed using Statistical Package for the Social Sciences (SPSS)-version 23 to identify predictors of surgical outcomes, with significance set at $p<0.05$. The study seeks to improve surgical techniques, enhance patient safety and provide insights into counseling and risk stratification for individuals with coloboma-associated cataracts.

Keywords: Manual small incision cataract surgery, Microcornea, Poor pupillary dilation, Visual rehabilitation, Zonular instability

INTRODUCTION

Coloboma, derived from the Greek term meaning "mutilation," refers to a defect caused by incomplete embryonal fissure closure. A "classic coloboma" is identified as a defect located in the infero-nasal region of the fundus, specifically linked to the failure of embryonal fissure closure. In contrast, defects found in other regions are classified as "atypical colobomas." Cataract formation is a common associated condition and remains the primary modifiable cause of defective vision in these cases. Subjects with iris coloboma, microcornea (horizontal diameter <10 mm) and irido-fundal coloboma exhibit a significantly higher incidence of nuclear sclerosis compared to the general population [1]. Structural anomalies, including microcornea, zonular deficiency, non-dilating pupils and lens coloboma, further complicate cataract surgery in these eyes, potentially impacting visual outcomes [2].

Cataracts tend to develop earlier in individuals with colobomatous eyes compared to their fellow eye. The anatomical features of coloboma, such as microphthalmos, small pupil and zonular weakness, pose challenges during cataract surgery [3,4]. Complications like hyphema, iritis and iris dialysis are more likely when iris repair methods, including pupilloplasty or artificial iris implantation, are performed concurrently with cataract surgery [5]. Despite the associated risks, such repairs are often necessary [6]. During the surgery, inserting an Intraocular Lens (IOL) of reduced diameter into the center of the capsular bag can create optical interfaces that may lead to visual distortions unless the colobomatous pupil is corrected [7].

Surgery is further complicated by structural issues such as microcornea, inadequate pupillary dilation, lack of zonules and lens abnormalities. Additionally, visual results are greatly affected by the extent of chorioretinal coloboma and optic disc irregularities. Although outcomes vary, several surgical procedures have been used to treat cataracts in colobomatous eyes, including PE, M-SICS, Intracapsular Cataract Extraction (ICCE) and Extracapsular Cataract Extraction (ECCE) [8,9].

Primary objective: To assess the safety and predictors of success for various surgical procedures for cataract surgery in eyes with colobomas at a tertiary care center in India.

Secondary objective: To compare surgical methods, specifically PE and M-SICS, to determine which yields better visual outcomes for patients.

Null hypothesis: There will be no change observed in the outcomes of different cataract surgeries for eyes affected by colobomas regarding safety and outcome predictors.

Alternate hypothesis: There will be differences in safety and outcome predictors between PE and M-SICS for eyes with colobomas.

REVIEW OF LITERATURE

In a study conducted by Franco JJ et al., a novel approach for treating iris coloboma in the eyes was discussed. This technique allowed controlled IOL decentration toward an inferior iris defect by creating an eccentric capsulorhexis and amputating one IOL haptic. This method produced positive results in two eyes, suggesting that it may provide a safer and more effective cataract surgery option for patients with iris coloboma, particularly in cases where iris restoration is impractical. Several related anatomical abnormalities can complicate cataract extraction in eyes with colobomas [10].

In a small observational series conducted by Sahay P et al., evidence was provided regarding the preferable method, risk factors and outcomes for cataract surgery in eyes affected by colobomas [9]. Chaurasia S et al., described uncomplicated PE in three eyes with microcornea and choroidal coloboma, as well as small incision cataract surgery in three eyes, two of which required anterior vitrectomy [4].

Kannan NB et al., revisited the historical technique of couching IOL in microphthalmic eyes with irido-fundal coloboma. Their method, which involves controlled lens dislocation into the vitreous cavity, showed positive results, with improved corrected distance visual acuity and manageable intraocular pressure. They emphasised the effectiveness and safety of this approach, especially for specific clinical characteristics, although long-term studies were recommended for more conclusive results [11]. Kohli G et al., indicated that both PE and M-SICS offer good postoperative outcomes and comparable risks. However, factors like microcornea, type 1 and type 2 coloboma and intraoperative complications were associated with poor visual outcomes [2].

MATERIALS AND METHODS

This is a hospital-based prospective interventional study that will be conducted at the Department of Ophthalmology at Acharya Vinobha Bhave Rural Hospital, Sawangi, Wardha, Maharashtra, India, under standard preoperative, intraoperative and postoperative conditions by a single experienced surgeon. The study will have a duration of two years (May 2024 - April 2026), during which 34 patients reporting to the Outpatient Department (OPD) will be selected for the study, taking the selection criteria into consideration. The author(s) have gathered and maintained documented ethical clearance in accordance with institutional and international standards. Institutional Ethical Approval (IEC) has been obtained: DHIMER (DU) IEC/2024/19, ECRI440/Inst/MH/2013/RR-2019 and the CTRI reference number is CTRI/2025/05/087449.

Sample size calculation: The patients will be allocated to two groups using simple random sampling: PE and M-SICS.

Sample size was estimated using the formula: $$n > Z^2_{1-\alpha}/2 \times p(1-p) / d^2$$

Where (α) =0.05

Estimated proportional (p)= 0.00085

Estimated error (d) = 0.01

The minimal sample size was set at 33, but for this study, the sample size will be 34 (17 for the study group and 17 for the control group) [2].

Inclusion criteria: The inclusion criteria will consist of patients who have consented to participate in the study and are within the age group of 45-70 years, regardless of sex. Patients with coloboma who have a cataractous lens and no history of previous ocular surgery in the operating eye will be included.

Exclusion criteria: Patients under the age of 45 or over 70 years will be excluded, along with those who have other ocular comorbidities, injuries, or previous surgeries. Cases with premature entry or where a valve could not be formed properly, as well as patients who are unwilling to participate in the study, will also be excluded.

Study Procedure

Data collection tools and process: A thorough history of the patients' symptoms, including onset, duration and any exacerbating factors, will be documented.

Every patient will undergo a detailed ocular examination, including:

1. Visual acuity test: This test measures how clearly someone can see at a specific distance, typically 20 feet (6 meters). It is a standard part of an eye exam that helps determine whether someone needs corrective lenses or if their vision is within normal limits. The test usually involves reading letters or symbols on a chart, with the smallest line that can be accurately read indicating the individual's visual acuity [12].
2. Slit lamp examination: This is a detailed eye exam that uses a microscope with a bright light source (the slit lamp) to visualise the eye's structures. It enables doctors to examine the cornea, lens, iris and retina to detect and diagnose a wide range of eye conditions [13].
3. Fundus examination: This examination may be conducted (if needed) where the lens is placed close to the eye to view the back of the eye (fundus).

The following tests will also be conducted:

- Keratometry (K1 and K2 values): Keratometry is a technique used to assess the curvature of the cornea (the transparent front portion of the eye). Its primary purposes are to diagnose and evaluate the degree of astigmatism and to assist in selecting the appropriate type and strength of corrective lenses. A keratometer that projects an image onto the cornea and measures the reflection to ascertain its curvature will be used for this test [14].
- Non-contact tonometry (IOP): Also known as air-puff tonometry, this method measures Intraocular Pressure (IOP) without coming into contact with the eye. It flattens the cornea with a puff of air, estimating the IOP by measuring the force required to do so. This screening technique is commonly employed and is particularly useful for children and patients who may find contact tonometry uncomfortable [15].
- SRK2 formula calculation: This refers to the process of calculating the power of an Intraocular Lens (IOL), which is a biometry technique. This calculation relies on accurate measurements of the patient's eye, including axial length and corneal power, along with an "A-constant" that varies depending on the specific IOL and surgeon [16].
- Cataract grading: Cataracts will be graded according to the Lens Opacity Classification System III, which is a robust and accurate means to classify cataracts as Nuclear Colour (NC), Nuclear Opalescence (NO), Cortical (C) and Posterior Subcapsular (P) and to grade them based on the extent into the lens according to an atlas of standardised slit-lamp retro illumination images [17].
- Chorioretinal coloboma grading: Patients will be classified according to the Ida Mann Classification.

Patients will be divided into two groups: one group will undergo PE and the other will undergo M-SICS. All surgeries will be performed by a single surgeon and the surgical technique will be determined based on the detection of the cataract [18].

The hardness of the cataract will be classified as "Soft" for NC 1-3 and "Hard" for NC 4-6 [18]. [Table/Fig-1] shows the corneal diameter and the grading according to the horizontal diameter.

Corneal diameter (horizontal)	Microcornea	Grading
(<8 Mm)	Severe microcornea	1
(8-10 Mm)	Mild-to-moderate Microcornea	2
(>10 Mm)	Normal	3

[Table/Fig-1]: Corneal diameter and the grading according to the horizontal diameter [2].

Surgical technique: The degree of microcornea severity, cataract hardness and zonular weakness will be taken into consideration when deciding between PE and SICS based on the type of cataract.

- PE will be the recommended option for eyes with mild cataracts and corneal diameters greater than 10 mm.
- PE will also be favored for eyes without zonular instability when the corneal diameter is between 8 and 10 mm and there is a hard cataract.
- For shallow anterior chambers and zonular loss, M-SICS will be the recommended modality for eyes with microcorneas measuring 6-8 mm or in the presence of hard cataracts.

The surgical approach will be modified according to the parameters set by the surgeon. In cases of severe zonular weakening, a Capsular Tension Ring (CTR) or Cionni ring will be employed. The timing for the CTR will vary based on the case specifics and the level of zonular weakness. The colobomatous region will be covered with dispersive viscoelastic material to prevent fluid misdirection during emulsification.

Patients will be re-evaluated on postoperative day 1, at the 1st week, 4th week and ultimately at the 6th week, depending on the healing process and any complications related to their particular needs [2]. These evaluations will include a thorough examination of the eyes, as shown in [Table/Fig-2].

Parameters	Specific parameters	Purpose/assessment goals
Preoperative parameters	Age, gender, eye involved	Baseline demographics
Preoperative parameters	Best Corrected Visual Acuity (BCVA)	Baseline visual function
Preoperative parameters	IOP	Safety and glaucoma risk
Preoperative parameters	Type and extent of iris coloboma [17]	Risk stratification and surgical planning
Preoperative parameters	Cataract grade and density [18]	Influences surgical technique and outcome
Preoperative parameters	Axial length and anterior chamber depth	Surgical planning and IOL calculation
Preoperative parameters	Co-morbidities (e.g., uveitis, lens subluxation)	Risk stratification
Preoperative parameters	Corneal endothelial cell count (if available)	Safety, risk of corneal decompensation
Intraoperative parameters	Duration of surgery	Efficiency and difficulty
Intraoperative Parameters	Need for iris manipulation or pupil expansion devices	Surgical complexity and tissue trauma
Intraoperative parameters	Complications (e.g., iris prolapse, posterior capsular rent)	Safety measure
Intraoperative parameters	Type of IOL implanted and centration	Refractive outcome and stability
Intraoperative parameters	Use of adjunctive procedures (e.g., iridoplasty, suturing)	To manage coloboma or complications
Postoperative parameters	BCVA at 1 week, 1 month, 3 months	Visual outcome over time
Postoperative parameters	IOP at 1 day, 1 week, 1 month	Monitoring for spikes or hypotony
Postoperative parameters	Anterior chamber reaction (cells/flare)	Inflammatory response
Postoperative parameters	Corneal clarity/edema	Safety and recovery
Postoperative parameters	IOL position and centration	Outcome and visual axis alignment
Postoperative parameters	Pupil shape and function post-op	Cosmesis and functional outcome
Postoperative parameters	Patient-reported outcomes (glare, photophobia, satisfaction)	Subjective satisfaction and quality of life
Postoperative parameters	Complications (e.g., CME, PCO, iris atrophy)	Late safety and effectiveness assessment
Postoperative parameters	Corneal topography or irregular astigmatism assessment	Evaluate corneal surface for surgical planning

[Table/Fig-2]: List of all the preoperative, intraoperative and postoperative parameters for PE and MSICS groups [2].
CME: Cystoid macular edema; PCO: Posterior capsule opacification

STATISTICAL ANALYSIS

A structured proforma will be used to gather data. A p-value of less than 0.05 will be considered statistically significant, while a p-value of less than 0.001 will be regarded as extremely significant. The data will be input into an MS Excel sheet and analysed using SPSS (version 23).

Authors' contribution: Authors assisted in data collection, provided feedback on the experimental design, contributed to data interpretation and reviewed the data.

REFERENCES

[1] Smelser GK. System of Ophthalmology, Normal and Abnormal Development; Part 1: Embryology. Arch Ophthalmol. 1965;74(4):553.
[2] Kohli G, Shah C, Sen A, Joshi R, Sood D, Patidar N, et al. Cataract surgery in eyes with associated coloboma: Predictors of outcome and safety of different surgical techniques. Indian J Ophthalmol. 2021;69(4):937-45.
[3] Mohamed A, Chaurasia S, Ramappa M, Sangwan VS, Jalali S. Lenticular changes in congenital iridolenticular choroidal coloboma. Am J Ophthalmol. 2014;158(4):827-30.
[4] Chaurasia S, Ramappa M, Sangwan VS. Cataract surgery in eyes with congenital iridolenticular choroidal coloboma. Br J Ophthalmol. 2012;96(1):138-40.
[5] Li J, Li Y, Hu Z, Kong L. Intraocular lens implantation for patients with coloboma of the iris. Exp Ther Med. 2014;7(6):1595-8.
[6] Phylactou M, Matarazzo F, Day AC, Hussain B, Maurino V. Cataract surgery in eyes with congenital ocular coloboma. Graefes Arch Clin Exp Ophthalmol. 2020;258(12):2753-9.
[7] Ogawa GSH. Congenital iris coloboma repair with excision of colobomatous sphincter muscle. J Cataract Refract Surg. 2021;47(8):1088-91.
[8] Khokhar S, Gupta S, Tewari R, Agarwal R, Gogia V, Sinha G, et al. Scleral tunnel phacoemulsification: Approach for eyes with severe microcornea. Indian J Ophthalmol. 2016;64(4):320-22.
[9] Sahay P, Maharana PK, Mandal S, Sinha R, Agarwal T, Sharma N, et al. Cataract surgery outcomes in eyes with chorioretinal coloboma. J Cataract Refract Surg. 2019;45(5):630-38.
[10] Franco JJ, Pineda R 2nd. Conforming to the anatomy and not the standard: A technique of eccentric capsulorrhexis and intraocular lens haptic amputation for eyes with iris coloboma. Eur J Ophthalmol. 2023;33(4):1740-45.
[11] Kannan NB, Goswami A, Vallinayagam M, Sarkar AD. Couching of cataractous lens in microphthalmic eyes with irido-fundal coloboma: Revisiting the historical technique. Int Ophthalmol. 2024;44(1):198.
[12] Caltrider D, Gupta A, Tripathy K. Evaluation of visual acuity. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 [cited 2025 Jun 2]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK564307/.
[13] Kaur K, Gurnani B. Slit-Lamp Biomicroscope. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 [cited 2025 Jun 2]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK587440/.
[14] Gurnani B, Kaur K. Keratometer. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 [cited 2025 Jun 2]. Available from: https://www.ncbi.nlm.nih.gov/sites/books/NBK580516/.
[15] Kempf R, Kurita Y, Iida Y, Kaneko M, Mishima HK, Tsukamoto H, et al. Understanding eye deformation in non-contact tonometry. Conf Proc IEEE Eng Med Biol Soc. 2006;2006:5428-31.

[16] Sanders DR, Retzlaff J, Kraff MC. Comparison of the SRK II formula and other second generation formulas. J Cataract Refract Surg. 1988;14(2):136-41.
[17] Lingam G, Sen AC, Lingam V, Bhende M, Padhi TR, Xinyi S. Ocular coloboma-A comprehensive review for the clinician. Eye (Lond). 2021;35(8):2086-109.
[18] Chylack LT, Wolfe JK, Singer DM, Leske MC, Bullimore MA, Bailey IL, et al. The lens opacities classification system III. The longitudinal study of cataract study group. Arch Ophthalmol. 1993;111(6):831-6.

PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Student, Department of Ophthalmology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.
2. Associate Professor, Department of Ophthalmology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Higher Education and Research, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Ashish Sharma,
Department of Ophthalmology, AVBRH, JNMC, Sawangi Meghe, Wardha, Maharashtra, India.
E-mail: sharma.ashish23788@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jan 31, 2025
- Manual Googling: Jun 07, 2025
- iThenticate Software: Jun 09, 2025 (12%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Jan 29, 2025**
Date of Peer Review: **Apr 05, 2025**
Date of Acceptance: **Jun 11, 2025**
Date of Publishing: **Jan 01, 2026**