

# Extended Depth of Focus Versus Monofocal Intraocular Lenses in Cataract Surgery: A Prospective Randomized Clinical Study of Visual and Patient-Reported Outcomes

Ankit S. Varshney\*, Divya Goyal, Hardeepsinh B. Mahida, Chetna S. Patel, Mahendrasinh D. Chauhan

Department of Optometry, Shree Bharatimaiya College of Optometry & Physiotherapy, Veer Narmad South Gujarat University, Surat, Gujarat 395007, India

E-mail: ankitsvarshney@yahoo.com

(Received: Jul 23, 2025, Revised: Aug 17, 2025, Accepted: Sep 06, 2025, Published: Sep 30, 2025)

**Abstract:** Cataract is the leading cause of reversible blindness worldwide, and intraocular lens (IOL) implantation is central to visual rehabilitation. Monofocal IOLs reliably restore distance vision but offer limited intermediate and near performance, resulting in continued dependence on spectacles. Extended depth of focus (EDOF) IOLs are designed to enhance functional vision across a broader range while preserving distance clarity. This prospective, randomized, assessor-masked clinical trial was conducted at Shree Bharatimaiya College of Optometry & Physiotherapy, Surat, India, between August 2024 and May 2025. Seventy-five patients were screened, and 60 eyes from 60 patients aged 50–75 years with age-related cataract were randomized 1:1 to receive either a monofocal or an EDOF IOL. Surgeries were performed using standardized phacoemulsification techniques. Primary outcomes at one month included uncorrected and best-corrected distance visual acuity (UDVA, BCDVA), uncorrected intermediate (UIVA) and near visual acuity (UNVA), refractive accuracy (spherical equivalent, SE), contrast sensitivity (Pelli-Robson), and patient-reported satisfaction using the Cataract 9SF questionnaire. Both groups achieved excellent UDVA and BCDVA ( $p > 0.05$ ), with similar refractive predictability (mean SE:  $-0.21 \pm 0.36$  D vs  $-0.18 \pm 0.39$  D;  $p = 0.64$ ). EDOF IOLs provided significantly better UIVA ( $0.18 \pm 0.09$  vs  $0.32 \pm 0.11$  logMAR;  $p < 0.001$ ) and UNVA ( $0.24 \pm 0.10$  vs  $0.38 \pm 0.12$  logMAR;  $p < 0.001$ ). Contrast sensitivity was marginally higher with monofocals ( $1.76 \pm 0.12$  vs  $1.68 \pm 0.15$ ;  $p = 0.047$ ). Patient-reported satisfaction and spectacle independence were significantly greater in the EDOF group ( $p < 0.05$ ). In conclusion, EDOF IOLs extend functional vision and improve spectacle independence compared with monofocals, with only a modest reduction in contrast sensitivity. These findings support EDOF IOLs as a patient-centered alternative in cataract surgery, with lens choice guided by lifestyle demands and expectations.

**Keywords:** Cataract surgery; Extended depth of focus intraocular lenses; Monofocal intraocular lenses; Visual acuity; Contrast sensitivity; Patient satisfaction; Spectacle independence

## I Introduction

Cataract remains the leading cause of blindness and visual impairment globally, accounting for nearly 45% of blindness and affecting more than 94 million people [1]. With life expectancy increasing worldwide, the burden of cataract is projected to rise, particularly in low- and middle-income countries where surgical coverage remains suboptimal. In India, cataracts contribute to approximately 66–80% of avoidable blindness, with an estimated 3.8–4.8 million new cases diagnosed annually [2,3]. Cataract surgery is one of the most frequently performed procedures in ophthalmology, with over 30 million cases annually worldwide, and its success largely depends on the implantation of an intraocular lens (IOL) to restore the refractive function of the crystalline lens [4].

Since the pioneering work of Harold Ridley in IOL development [5], IOL technology has advanced

substantially. Historically, monofocal IOLs have been the standard of care, providing excellent uncorrected distance visual acuity but requiring spectacles for intermediate and near tasks such as reading or computer use [6]. With increasing patient expectations for spectacle independence and improved functional vision, premium IOLs have been developed to address these limitations [7].

Extended depth of focus (EDOF) IOLs represent a significant innovation in presbyopia-correcting technology. Unlike multifocal IOLs, which split light into distinct focal points and may cause photic disturbances, EDOF lenses extend the depth of focus, thereby improving intermediate and near vision while maintaining distance clarity [8,9]. Clinical trials have shown that EDOF IOLs enhance visual performance for daily tasks such as digital device use and driving dashboard viewing, while reducing spectacle dependence [10,11]. However, some concerns remain regarding possible reductions in contrast sensitivity compared to monofocal IOLs [12].

Despite extensive evaluation of EDOF lenses in Western populations, there is limited randomized controlled trial (RCT) evidence from India. Given the large cataract burden and the need for solutions that balance functional outcomes with accessibility, comparative studies in this context are essential. This study was therefore designed as a prospective, randomized clinical trial to compare postoperative visual outcomes, refractive predictability, contrast sensitivity, and patient-reported satisfaction between patients implanted with EDOF and monofocal IOLs.

## II Materials and Methods

### II.a Study Design and Ethical Approval

This prospective, randomized, parallel-group clinical trial was conducted at Shree Bharatimaiya College of Optometry & Physiotherapy, Surat, India, between August 2024 and May 2025. The protocol was approved by the Institutional Ethics Committee and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrolment.

### II.b Sample Size and Participants

Seventy-five patients with age-related cataract were screened for eligibility. The sample size was calculated a priori, assuming a mean difference of 0.1 logMAR in uncorrected intermediate visual acuity (UIVA) between groups, a standard deviation of 0.15, a two-tailed  $\alpha$  of 0.05, and power of 80%. This yielded a minimum of 25 eyes per group; to allow for attrition, 30 patients were recruited into each arm.

Inclusion criteria were: age 50–75 years, clinically significant cataract, no prior ocular surgery, and absence of ocular comorbidities. Exclusion criteria included corneal opacity, glaucoma, retinal pathology, systemic or ocular conditions affecting vision, and intraoperative complications. Of the 75 screened, 15 were excluded due to ineligibility or refusal, leaving 60 patients (60 eyes) for randomization.

### II.c Randomization and Blinding

Eligible patients were randomized in a 1:1 ratio to receive either a monofocal IOL (monofocal group) or an extended depth of focus IOL (EDOF group) using a computer-generated random sequence. Allocation concealment was maintained using sealed opaque envelopes. Surgeons were necessarily aware of lens allocation; however, patients and postoperative outcome assessors were masked to group assignment to minimize performance and detection bias. All patients completed surgery and follow-up without protocol deviations or attrition (Figure 1).

### II.d Surgical Procedure

All surgeries were performed by experienced cataract surgeons using a standardized phacoemulsification technique under topical or peribulbar anesthesia. A 2.8 mm clear corneal incision was fashioned,

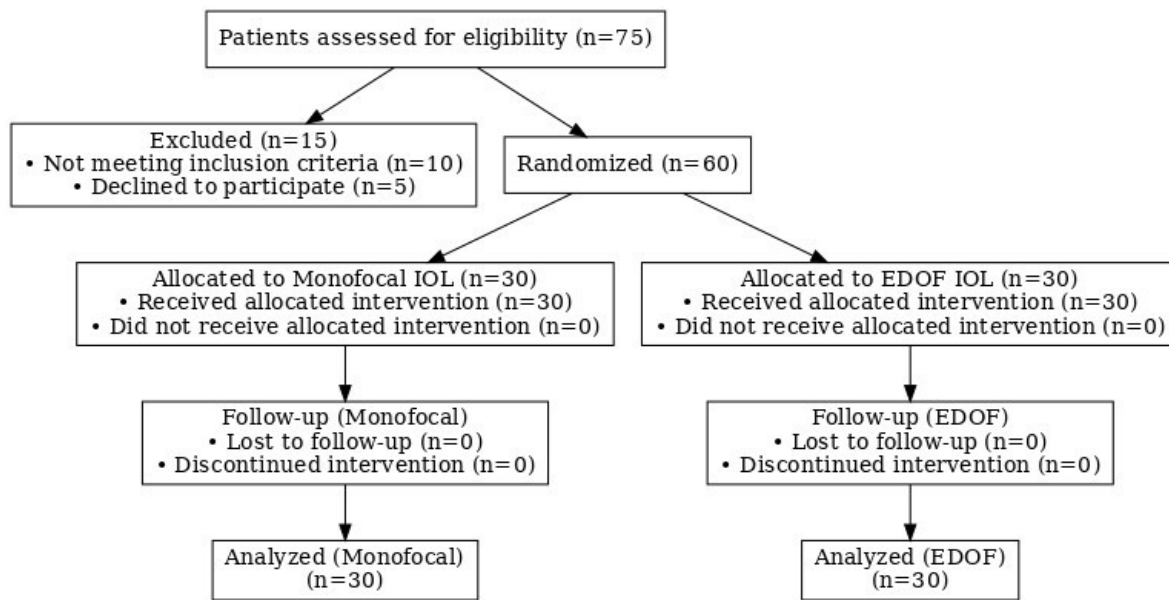


Figure 1: CONSORT flow diagram of patient screening, randomization, allocation, and follow-up. Of 75 patients screened, 60 were randomized equally to monofocal and EDOF IOL groups, with no losses to follow-up.

followed by continuous curvilinear capsulorrhexis, nucleus emulsification, and cortical aspiration. The allocated foldable posterior chamber IOL (monofocal or EDOF) was implanted in the capsular bag using an injector system. Postoperative care was uniform across groups and included a tapered regimen of topical antibiotics and corticosteroids for four weeks.

## II.e Postoperative Assessments

Patients were evaluated one month postoperatively. Outcome measures included:

- *Visual acuity*: Uncorrected distance visual acuity (UDVA) at 6 meters using Snellen and ETDRS charts; best-corrected distance visual acuity (BCDVA) following manifest refraction; uncorrected intermediate visual acuity (UIVA) at 60–80 cm using reduced Snellen charts; and uncorrected near visual acuity (UNVA) at 35–40 cm using Jaeger charts.
- *Refraction*: Spherical equivalent (SE) determined by autorefractometry and confirmed with subjective refraction.
- *Contrast sensitivity*: Assessed monocularly at 1 meter under photopic conditions using the Pelli-Robson chart.
- *Patient-reported outcomes*: Evaluated with the validated Cataract 9-Item Short Form (Cataract 9SF) questionnaire, assessing daily visual function, spectacle dependence, and overall satisfaction.

## II.f Statistical Analysis

All analyses were performed using SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean  $\pm$  standard deviation (SD) and compared between groups using the independent-samples t-test for normally distributed data or the Mann–Whitney U test for skewed data. Categorical variables were analyzed with the chi-square test or Fisher’s exact test as appropriate. A two-sided p-value  $<0.05$  was considered statistically significant.

Table 1: Baseline patient distribution by intraocular lens (IOL) type (monofocal vs extended depth of focus [EDOF]).

Characteristic	Monofocal IOL (n = 30)	EDOF IOL (n = 30)	p-value
Mean Age (years)	63.5 $\pm$ 5.4	62.8 $\pm$ 6.1	0.68
Male (%)	53.3	50.0	0.79
Female (%)	46.7	50.0	0.79
Baseline UDVA (logMAR)	0.74 $\pm$ 0.18	0.71 $\pm$ 0.20	0.56
Baseline BCDVA (logMAR)	0.46 $\pm$ 0.15	0.44 $\pm$ 0.17	0.61
Hypertension (%)	16.7	20.0	0.74
Diabetes Mellitus (%)	13.3	10.0	0.69
Laterality (Right eye %)	56.7	53.3	0.80

Values are mean  $\pm$  SD or percentages. UDVA = uncorrected distance visual acuity; BCDVA = best-corrected distance visual acuity.

Table 2: Postoperative spherical equivalent (SE) refractive accuracy in monofocal and EDOF groups.

Parameter	Monofocal IOL (n = 30)	EDOF IOL (n = 30)	p-value
Spherical Equivalent (D)	-0.21 $\pm$ 0.36	-0.18 $\pm$ 0.39	0.64

Values are mean  $\pm$  SD. No significant difference between groups.

### III Results

A total of 60 patients (60 eyes) completed the trial, with 30 eyes implanted with monofocal intraocular lenses and 30 eyes with extended depth of focus (EDOF) intraocular lenses. Of the 75 patients screened, 15 were excluded due to ineligibility or refusal to participate. No intraoperative complications or postoperative losses to follow-up occurred, ensuring complete dataset analysis.

#### III.a Baseline Characteristics

Baseline demographic and clinical parameters were well balanced between the groups (Table 1). The mean age was comparable (63.5  $\pm$  5.4 years in the monofocal group vs 62.8  $\pm$  6.1 years in the EDOF group,  $p = 0.68$ ). Gender distribution was similar (male: 53.3% vs 50.0%), as were systemic comorbidities such as hypertension and diabetes mellitus. Laterality distribution and baseline visual acuities (UDVA and BCDVA) also showed no significant differences, confirming group homogeneity prior to surgery (Figures 2 and 3).

#### III.b Refractive Outcomes

Postoperative refractive predictability was high and equivalent in both cohorts. At one month, the mean spherical equivalent (SE) was -0.21  $\pm$  0.36 D in the monofocal group and -0.18  $\pm$  0.39 D in the EDOF group ( $p = 0.64$ ; 95% CI -0.21 to 0.14), demonstrating excellent accuracy of biometry and surgical technique across both IOL types (Table 2; Figure 4). Both groups clustered closely around emmetropia, with no outliers exceeding  $\pm 1.0$  D.

#### III.c Distance Visual Acuity

Both groups achieved excellent distance visual acuity at one month. The mean UDVA was 0.05  $\pm$  0.08 logMAR for monofocal IOLs and 0.06  $\pm$  0.07 logMAR for EDOF IOLs ( $p = 0.72$ ), while mean BCDVA

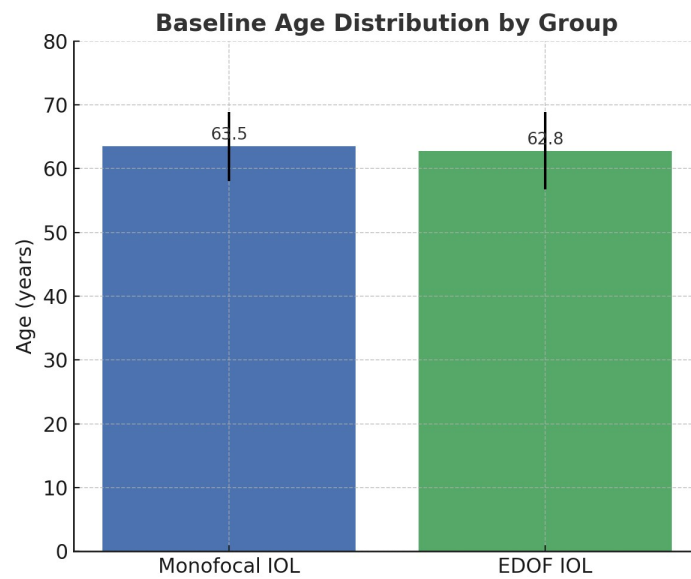


Figure 2: Age group distribution of patients by IOL type.

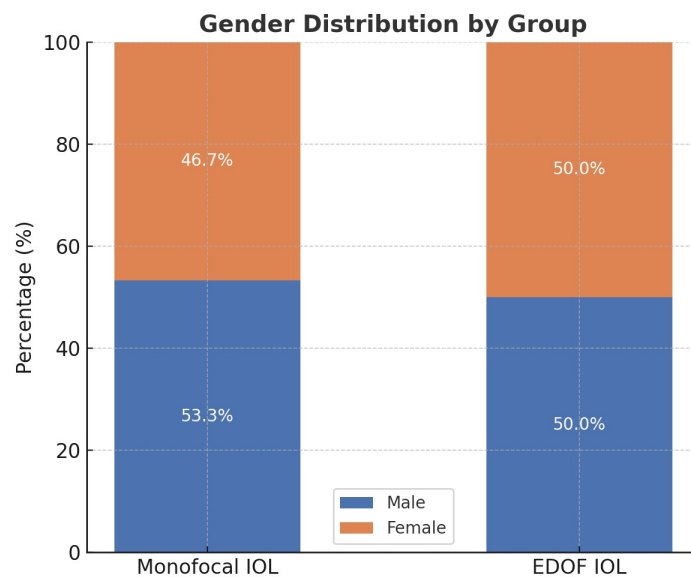


Figure 3: Gender distribution among patients receiving monofocal and EDOF IOLs.

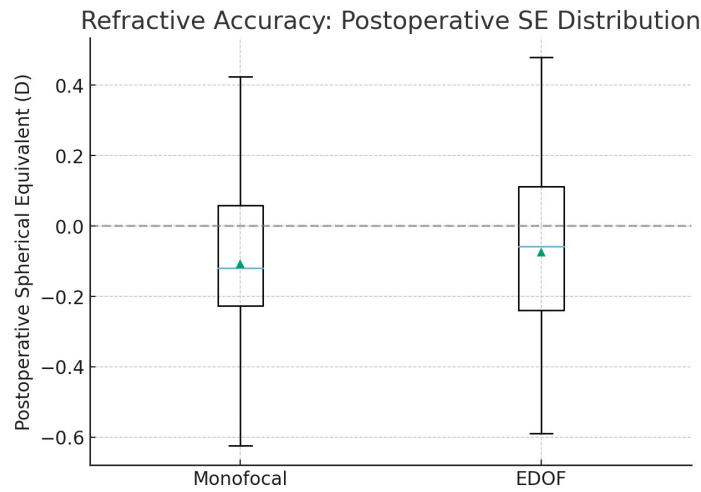


Figure 4: Postoperative spherical equivalent (SE) in monofocal and EDOF IOL groups. Box plots show median, range, and mean, demonstrating similar refractive accuracy with clustering around emmetropia.

Table 3: Comparison of postoperative distance visual acuity (UDVA) between monofocal and EDOF groups (logMAR).

Parameter	Monofocal IOL	EDOF IOL	p-value
UDVA (logMAR)	0.05 ± 0.08	0.06 ± 0.07	0.72
BCDVA (logMAR)	0.02 ± 0.05	0.03 ± 0.06	0.81

was  $0.02 \pm 0.05$  logMAR and  $0.03 \pm 0.06$  logMAR, respectively ( $p = 0.81$ ). No statistically significant differences were observed, confirming equivalence in distance vision outcomes (Table 3).

III.d Intermediate and Near Visual Acuity

In contrast, marked differences emerged in intermediate and near visual performance. Patients with EDOF IOLs demonstrated significantly superior uncorrected intermediate visual acuity (UIVA:  $0.18 \pm 0.09$  logMAR vs  $0.32 \pm 0.11$  logMAR,  $p < 0.001$ ; 95% CI 0.09–0.19) and uncorrected near visual acuity (UNVA:  $0.24 \pm 0.10$  logMAR vs  $0.38 \pm 0.12$  logMAR,  $p < 0.001$ ; 95% CI 0.08–0.18) compared with monofocal recipients (Table 4; Figure 5). These findings highlight the extended functional range achieved by EDOF lenses.

III.e Contrast Sensitivity

Mean contrast sensitivity, measured with the Pelli-Robson chart, was slightly higher in the monofocal group ( $1.76 \pm 0.12$ ) compared with the EDOF group ( $1.68 \pm 0.15$ ), with the difference reaching borderline

Table 4: Comparison of postoperative uncorrected intermediate visual acuity (UIVA) and near visual acuity (UNVA) between monofocal and EDOF groups (logMAR).

Parameter	Monofocal IOL	EDOF IOL	p-value
UIVA (logMAR)	0.32 ± 0.11	0.18 ± 0.09	<0.001
UNVA (logMAR)	0.38 ± 0.12	0.24 ± 0.10	<0.001

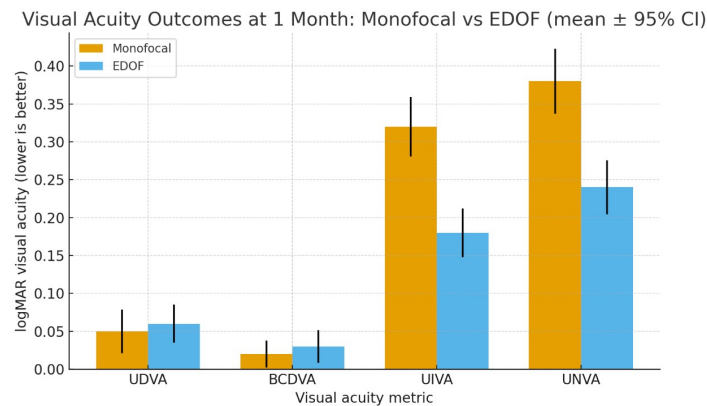


Figure 5: One-month visual acuity outcomes (logMAR) for monofocal and EDOF IOLs. Bars show mean  $\pm$  95% CI. Distance vision (UDVA, BCDVA) was comparable, while EDOF achieved significantly better intermediate (UIVA) and near (UNVA) acuity.

Table 5: Postoperative contrast sensitivity (Pelli-Robson scores) in monofocal vs EDOF groups.

Parameter	Monofocal IOL	EDOF IOL	p-value
Contrast Sensitivity (score)	1.76 $\pm$ 0.12	1.68 $\pm$ 0.15	0.047

statistical significance ( $p = 0.047$ ; 95% CI 0.001–0.15). Despite this reduction, both groups-maintained values within the normal clinical range, suggesting preserved functional image quality (Table 5; Figure 6).

### III.f Patient-Reported Outcomes

Subjective outcomes further favored EDOF IOLs. Based on the Cataract 9SF questionnaire, 86.7% of EDOF patients reported either "no difficulty" or "mild difficulty" in performing intermediate and near tasks, compared with 63.3% in the monofocal group ( $p = 0.02$ ). Spectacle independence was also substantially greater in the EDOF cohort (80.0% vs 40.0%,  $p = 0.004$ ). Overall satisfaction was significantly higher among EDOF recipients, reflecting their broader range of unaided functional vision (Table 6; Figure 7).

### III.g Composite Visual Performance

To provide a global overview, a composite radar chart was generated summarizing all endpoints, including distance, intermediate, and near visual acuity, contrast sensitivity, and patient-reported outcomes. This profile clearly illustrated the superior functional range and satisfaction achieved with EDOF lenses compared to monofocals (Figure 8).

Table 6: Patient satisfaction and spectacle independence based on Cataract 9SF questionnaire.

Parameter	Monofocal IOL (%)	EDOF IOL (%)	p-value
High Satisfaction	63.3	86.7	0.02
Spectacle Independence	40.0	80.0	0.004

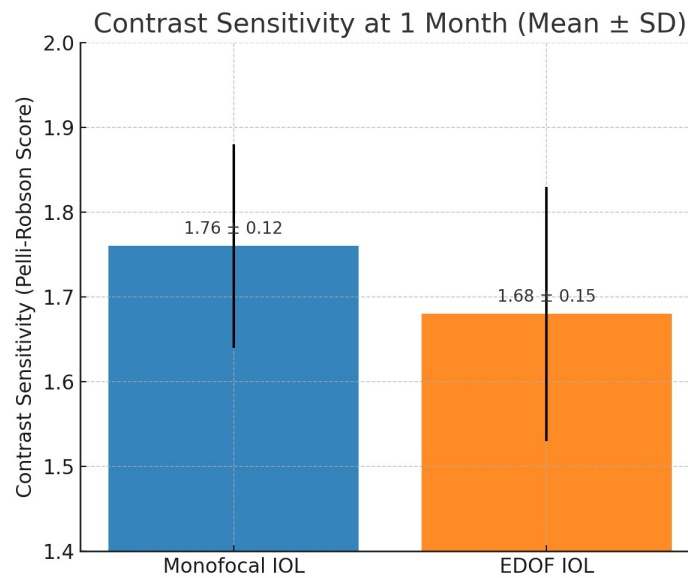


Figure 6: Postoperative contrast sensitivity (mean  $\pm$  SD, Pelli-Robson scores) comparing monofocal and EDOF IOL groups.

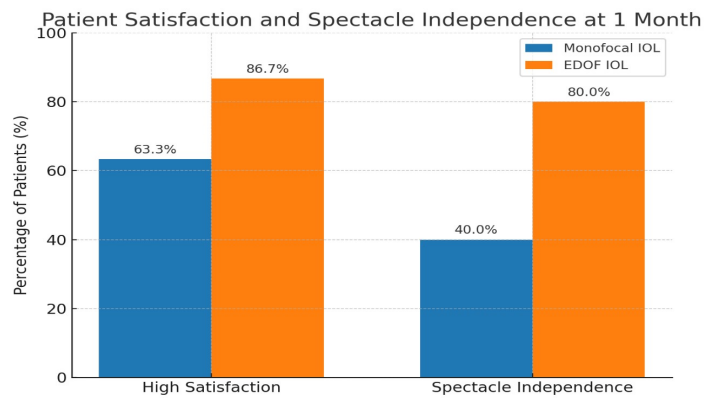


Figure 7: Patient-reported satisfaction and spectacle independence after cataract surgery with monofocal and EDOF IOLs (stacked bar chart).



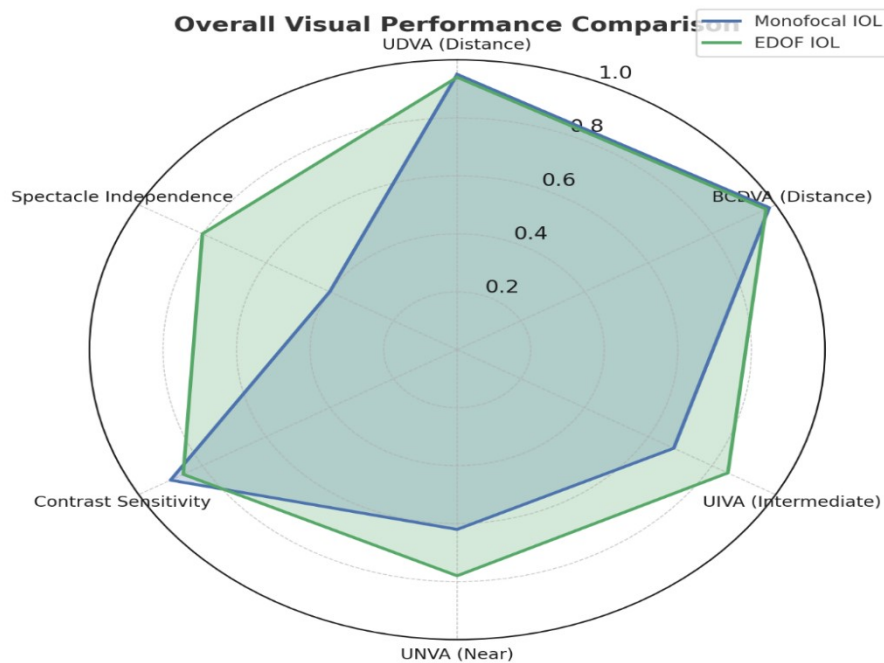


Figure 8: Radar Chart comparing overall performance (Monofocal vs. EDOF IOLs).

## IV Discussion

This randomized clinical trial demonstrated that extended depth of focus (EDOF) intraocular lenses provide superior intermediate and near visual acuity, greater spectacle independence, and higher patient satisfaction compared with monofocal lenses, while maintaining equivalent distance vision and refractive predictability. These findings are particularly relevant in the current era, where visual demands extend beyond distance clarity to include intermediate tasks such as computer and digital device use.

Distance visual acuity outcomes were excellent in both groups, with no statistically significant differences in uncorrected (UDVA) or best-corrected distance visual acuity (BCDVA). This result is consistent with previous studies by [10] and [11], which confirmed that the optical design of EDOF lenses preserves distance clarity comparable to standard monofocal IOLs. The present findings therefore reinforce that premium IOL technologies can achieve distance outcomes equivalent to traditional lenses, addressing concerns of potential trade-offs.

The most striking differences emerged in intermediate and near vision. Patients implanted with EDOF IOLs demonstrated significantly better uncorrected intermediate visual acuity (UIVA) and uncorrected near visual acuity (UNVA) compared to those receiving monofocals. This aligns with reports by [9] and [13], who showed that the elongated focal range of EDOF designs improves functional vision across a broader spectrum. Such improvements are of growing clinical importance, as modern lifestyles increasingly depend on intermediate vision for computer work, dashboard viewing, and mobile device use. By extending functional vision without creating multiple discrete foci, as seen in multifocal IOLs, EDOF lenses provide a physiologically smoother visual experience with fewer photic disturbances.

Refractive accuracy was excellent in both groups, with postoperative spherical equivalents close to emmetropia. These results corroborate earlier findings by [14] and [15], confirming that with modern biometry and IOL power calculation formulas, both monofocal and EDOF lenses achieve highly predictable refractive outcomes. This reliability ensures that outcome differences between IOL types reflect optical design characteristics rather than refractive bias.

A slight reduction in contrast sensitivity was observed in the EDOF group compared to monofocals, although values remained within clinically acceptable ranges. This trend has been consistently reported in previous trials [11,12]. The likely mechanism is the more complex optical profile of EDOF lenses, which redistributes light to extend the depth of focus at the expense of minor contrast loss. Clinically, however, this reduction was not perceived as functionally debilitating, and patients generally accepted the trade-off in exchange for reduced spectacle dependence and improved near/intermediate vision.

Patient-reported outcomes further reinforced the superiority of EDOF lenses in functional daily life. Higher satisfaction rates and greater spectacle independence observed in the EDOF cohort mirrored findings from [10] and [16]. These subjective measures are critical, as cataract surgery today is not only a vision-restoring procedure but also a refractive intervention aimed at optimizing quality of life. The ability of EDOF IOLs to provide functional independence across a wide visual range strongly influences patient acceptance and satisfaction.

The clinical implications of these findings are substantial. In counseling patients, monofocal lenses remain an excellent option for those prioritizing distance clarity, cost-effectiveness, and maximal contrast sensitivity. However, for patients seeking broader visual function and reduced dependence on spectacles—particularly younger, working-age, or digitally active individuals—EDOF lenses represent a valuable alternative. Cost remains a significant barrier in low- and middle-income countries such as India, where monofocals dominate due to affordability and public health priorities [15]. As demand for premium IOLs rises, cost-effectiveness and equitable access will become central issues in surgical planning and policy.

This study has several limitations. The modest sample size and single-center design limit generalizability, while the short follow-up (one month) precludes evaluation of long-term outcomes such as posterior capsule opacification, dysphotopsia, and sustained patient satisfaction. Although patients and assessors were masked, surgeons were not, introducing potential performance bias. Despite these limitations, the randomized design and standardized surgical technique strengthen the validity of the findings.

Future research should include larger, multicenter randomized controlled trials with extended follow-up to assess long-term stability of outcomes, incidence of visual disturbances, and posterior capsule opacification rates. Additionally, cost-effectiveness analyses and quality-of-life studies are particularly relevant in resource-constrained settings, where access to premium IOLs is limited.

In summary, this trial adds to growing evidence that EDOF IOLs deliver a broader range of functional vision and higher patient satisfaction than monofocal lenses, with only a modest trade-off in contrast sensitivity. These results underscore the clinical value of EDOF lenses as a patient-centered alternative in modern cataract surgery and highlight the need to integrate lifestyle demands, cost, and accessibility into individualized IOL selection.

## V Conclusion

Extended depth of focus intraocular lenses provide a broader range of functional vision, with significant gains in intermediate and near visual acuity compared to monofocal lenses. While monofocal IOLs retain a marginal advantage in contrast sensitivity, the reduction observed with EDOF lenses remained within clinically acceptable limits and did not compromise overall performance. Importantly, patients implanted with EDOF lenses experienced higher satisfaction and greater spectacle independence, underscoring their value in enhancing quality of life after cataract surgery. These findings support the role of EDOF IOLs as a reliable and patient-centered alternative to monofocal IOLs in modern cataract practice. Future multicenter trials with larger cohorts, longer follow-up, and cost-effectiveness analyses are warranted to confirm these results, assess long-term visual stability, and inform decision-making in diverse healthcare settings.

## VI Key Clinical Message

Extended depth of focus intraocular lenses provide superior intermediate and near vision with higher patient satisfaction and spectacle independence compared to monofocal lenses, while maintaining comparable distance acuity. Although a slight reduction in contrast sensitivity is observed, it remains clinically acceptable, making EDOF IOLs a valuable option in modern cataract surgery when tailored to patient lifestyle and expectations.

## Acknowledgements

The authors gratefully acknowledge the patients who participated in this study and the surgical team at Shree Bharatimaiya College of Optometry & Physiotherapy, Surat, India, for their invaluable support during data collection and follow-up. We also extend our appreciation to the clinical staff and optometrists who assisted with visual function assessments and patient-reported outcome surveys. Special thanks are due to the institutional ethics committee for their guidance and oversight throughout the trial.

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