ORIGINAL ARTICLE

Patient Satisfaction Level and Vision-Related Quality of Life: A Comparison between Trifocal and Diffractive Extended Depth of Focus (EDOF) IOLs

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ABSTRACT

OBJECTIVE: To compare patient satisfaction level and vision-related quality of life after Trifocal and EDOF implants to treat cataracts among the population of Southern Punjab.

METHODOLOGY: This comparative practice-based study was conducted at the Sight Centre of Bahawalpur City of Southern Punjab from August 2022 to July 2023. Informed consent was obtained from all the subjects. A total of n=120 eyes were operated in two EDOF and Trifocal treatment cohorts. VR-QOL was assessed for near, intermediate, and distant vision. The data was analyzed on SPSS version 27. The p-value < 0.05 was considered statistically significant.

RESULTS: There were n=29 (48.3%) males and n=31 (51.6%) females. The majority n=21 (35%) of subjects were aged 40-49. It was revealed that trifocal IOL demonstrated improved mean rank for near and intermediate vision. Statistically, a significant difference was found between putting thread into the needle and the mobile phone's utility at p-values of 0.047 and 0.040, respectively. Trifocal IOLs frequently generated the halo photic effect for light scattering at a P-value of 0.0001. Significant improvement was revealed in the VA of both eyes. The vision was improved (100%) with both Trifocal and EDOF group treatment options. Both treatment cohorts were satisfied with the final surgical outcome.

CONCLUSION: VA was improved after implanting Trifocal and EDOF IOLs. Trifocal IOL demonstrated better performance at near & distant vision. The halo photic effect was generated more frequently by the trifocal IOLs. Patients were equally satisfied with the surgical outcome of both treatment options.

KEYWORDS: Cataract, Corrected Near Visual Acuity (CNVA), Extended Depth of Focus (EDOF), Intraocular Lens, Trifocal, Visual Related Quality of Life (VR-QOL), Uncorrected Near Visual Acuity (UNVA), Uncorrected Intermediate Visual Acuity (UIVA).

INTRODUCTION

Vision-related quality of life (VR-QOL) is affected by visual impairment caused by cataracts¹. It affects 90% of the older population from 65 years and over². According to the WHO report of 2021, visual impairment and blindness greatly influence a person's ability to perform daily tasks such as managing the household, cooking, driving, performing at work, reading newspaper, recreational/leisure activities and watching news, etc³. Among older adults, social isolation, the risks of falls, fear of falling, lack of participation⁴ in social gatherings, and restriction in physical activities⁵ can lead to depression⁶ due to visual disturbance. Thereby, quality of life deteriorates due to visual impairment and among elder's increases anxiety disorders more rapidly as compared to the elders without visual impairment⁷.

Phacoemulsification with IOL implantation has been reported as a cost-effective treatment for treating cataract-related visual impairment and enhancing QOL among individuals in developed and developing countries⁸. During the last decades, various types of intraocular lenses (IOL) have been implanted in phacoemulsification procedures to treat cataracts' visual impairment. Literature reported that bifocal IOL provides similar visual acuity (VA) at near and distant vision and better outcomes at intermediate distant range (50-100cm) than standard monofocal IOL⁹. Most individuals depend on intermediate vision, which includes cooking, working a computer, socializing, controlling the car dashboard, eating, and shopping. Hence, bifocal IOL is a realistic option for performing daily activities. On the other hand, a trifocal lens splits lights into three different focal points to provide comparable VAs at all distances¹⁰.

Per PI's knowledge, there is a lack of literature available to compare the Trifocal and EDOF IOLs in this region of Southern Punjab. Therefore, this would be the first significant study conducted in Southern Punjab, Pakistan, to compare patient satisfaction & VR-QOL among cataract patients treated with (EDOF) and trifocal lenses; indeed, it was the study's rationale. The study compared patient satisfaction levels and Vision-Related Quality of Life after EDOF and Trifocal Lens implants for cataract treatment.

METHODOLOGY

This comparative prospective practice-based study was conducted at Sight Centre of Bahawalpur City of Southern Punjab from August 2022 till July 2023. This study followed the study protocol of Helsinki. It was approved by the PI (HOD of the ophthalmology unit at Bahawalpur Medical College, BMC), the only ophthalmologist performing all cataract surgeries with EDOF and trifocal IOLs of the same company to validate the result outcomes. Moreover, ethical approval was obtained from IRB of BMC letter No. 03/2022. A total of n=60 subjects were selected and divided into two treatment groups of Trifocal IOLs n=30 and (EDOF) n=30 based on the affordability of the treatment cost. Hence, a total of n=120 eyes were operated in two treatment cohorts. Informed consent was obtained from included patients. Subjects who underwent bilateral cataract extraction surgery lived an active life, had no co-morbidities and from 20-65 years of age and were implanted either with EDOF IOLs or trifocal IOLs were included. Subjects associated with any ocular pathology, corneal opacities, diabetes retinopathy, night blindness, age-related macular degeneration, pigmentosa, retinitis, macular holes, bedridden and dementia patients were excluded. The data was collected on tailor-made proforma after an extensive literature search. The study tool was constructed by considering the vital domains of patients' lives which can be affected after surgery to measure visual functional recovery. Four consultant ophthalmologists validated the tool. The first section was about demographic data; pre- & postoperative visual acuity was assessed, and VR-QOL was recorded based on near, intermediate, and distant vision, with three items each. The responses were recorded on a threepoint Likert scale rated 1=agree, 2=neutral and 3=disagree. Patient satisfaction with the final surgical outcome was extracted from Monestam E 1999¹¹ which had three items: improvement of vision, improved QOL, and whether surgery meets your expectations. The items had yes and no responses. The data was analyzed on SPSS version 27. The normality of data was checked with the help of the Shapiro-Wilk test. The Mann-Whitney U test was performed to compare the mean rank of two treatment groups. The p-value < 0.05 was considered statistically significant.

RESULTS

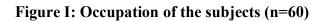
There were a total of n=60 subjects, from which n=29 (48.3%) were female and n=31 (51.6%) were males. The majority n=21 (35%) of subjects were from 40-49 years of age, and the majority n=26 (43.3%) were graduated. Among gender and cataract treatment groups, a statistically significant difference was found at a p-value of 0.060 **Table I**. Most females were housewives **Figure I**. Comparing the VR-QOL in both cohorts revealed that trifocal IOL demonstrated an improved mean rank for near vision and intermediate vision. Statistically, a significant difference was found between putting thread into the needle and the mobile phone's utility at p-values of 0.047 and 0.040, respectively. The halo photic effect was generated more frequently by the trifocal IOLs. The mean rank was improved in the EDOF IOL group in a reading score of a cricket match and the time on the wall clock as 31.88 and 32.53, respectively, but a significant difference was found for the scattering of light at P-value 0.0001 **Table II**. The bilateral visual acuity after the surgery was assessed in EDOF and Trifocal groups, and significant improvement was observed in VA in both eyes.

The vision was improved among 100% of the subjects with both Trifocal and EDOF group treatment options. Patients were satisfied with the final surgical outcome of both trifocal and EDOF IOLs **Figure II**.

Demographic Data		EDOF N=30	Trifocal N=30	P-Value
Gender	Male	12	19	0.060*
	Female	18	11	0.000*
Age	30-39 Years	8	4	
	40-49 Years	11	10	0 510**
	50-59 Years	6	9	0.510**
	>/= 60 Years	5	7	
Education	Below Matric	8	3	
Level	Matric	4	4	
	Intermediate	6	7	0.342**
	Graduation	12	14	
	Uneducated	0	2	
Living	Urban	17	15	0.000t
Area	Rural	13	15	0.398*

Table I: Demographics of EDOF and Trifocal Groups for Cataract Surgery

*Fischer' Exact Test, **Chi Square



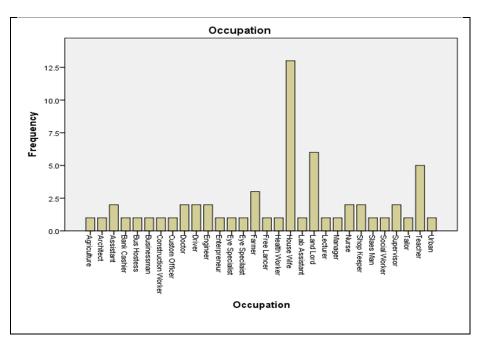


Table II: Comparing the Mean Rank of	VR-QOL parameters in	EDOF and Trifocal Lens
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VR-QOL Parameters		EDOF	Trifocal	P-value
Near Vision	Threads into needle	26.65	34.35	0.047*
	Read Quran-e-Pak	28.60	32.40	0.300
	Use Mobile Phone	26.92	34.08	0.040*
Intermediate	Perform cooking	28.50	32.50	0.088*
Vision	Use computer	29.50	31.50	0.154
	See speedometer	30.97	30.03	0.584
Distant	Read the score of a cricket match	31.88	29.12	0.379
Vision	See the time on the wall clock	32.53	28.47	0.083*
	Scattering of Light (Glare, halo)	23.45	37.55	0.000*
	Scattering of Light (Glare, halo)			

Mann-Whitney U Test, Asymp.Sig. (2 tailed)

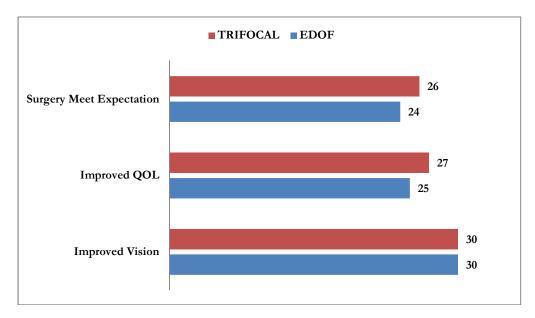


Fig II: Patient Satisfaction Level with Final Surgical Outcome of IOLs

DISCUSSION

This study aimed to compare Patient Satisfaction Level and VR-QOL with clinical outcomes among cataract patients following the implantation of trifocal intraocular lenses (IOLs) and (EDOF) IOLs. The study provides the most recent and reliable evidence to assist in selecting appropriate IOLs for patients. The analysis of this study revealed that trifocal IOLs demonstrated superior uncorrected near visual acuity (UNVA) compared to EDOF-IOLs, supported by highquality evidence. However, the EDOF group exhibited better results in uncorrected intermediate visual acuity (UIVA). Furthermore, freedom from spectacles for near vision was achieved among subjects of the trifocal group. Still, photic effects such as glare and halos were experienced more in this trifocal group.

The result of this study is in unity with the study of de Medeiros et al.¹⁴ regarding patient satisfaction level and visual outcomes for trifocal and (EDOF) which indicated that trifocals performed better in near visual acuity. Moreover, both trifocals and EDOFs demonstrated comparable "excellent" distance and intermediate visual acuity levels. Additionally, a high percentage of patients in both groups achieved spectacle independence, and disturbing photic phenomena were minimal.

de Medeiros et al.¹⁴ compared the visual outcomes and clinical performance of trifocal and EDOF lenses for six months. In this study, a total of 52 eyes of 26 patients for bilateral cataract surgery were divided into two groups: group A received trifocal lenses (FineVision, PhysIOL, not approved in the United States) and group B received EDOF lenses (Tecnis Symfony). Both groups had improved subjective quality of vision on short, intermediate and long distances.

Based on a meta-analysis by Bourne RRA et al⁹, it was found that trifocals outperformed multifocal with two focal points in terms of intermediate vision. The study compared the clinical performance of these two types of lenses. Similarly, a study conducted by Miyata K in 2021⁵ revealed that trifocals were superior to bifocal multifocal in intermediate vision. Additionally, trifocals provided comparable or better distance and near vision without compromising visual quality.

Packer M 2003¹³ discussed visual function as a daily activity directly affecting QOL. The outcome of presbyopia, refractive lens exchange (RLE) surgery and cataract surgery is to achieve a full range of vision from near to far and to get freedom from the spectacles.

Literature supported the superiority of trifocal IOLs over mono-focal and bifocal lenses due to the better near and intermediate vision in various meta-analyses and clinical studies¹⁴⁻¹⁶.

Another aspect that has received limited attention in this study pertains to patients' quality of vision, eye care habit and life experiences. Patients subjective benefits and the attainment of freedom from spectacle over time are crucial factors that influence their expectations. In this study, approximately 80% of patients achieved spectacle independence following the implantation of multifocal IOLs. This study evaluated Spectacle independence across all distances to provide a more comprehensive perspective. Strong evidence indicated that more patients in the trifocal group achieved spectacle independence at near distances observed. However, as spectacle dependence is a subjective assessment influenced by individual habits and real-life contexts, caution should be exercised when interpreting this conclusion.

Any disruption in the transmission of light through the optical axis can result in subjective misperception and various types of photopsia, with glare and halos being the most commonly reported photic effects. Factors such as cataracts or multifocal IOLs can contribute to these disturbances. While up to 90% of patients reported experiencing halos following trifocal IOL

implantation in the current study, these effects were generally not considered bothersome in the majority of cases. However, it is essential to note that most studies reported the presence of glare and halos based on subjective reports, lacking an objective evaluation system¹⁷. An inconsistent conclusion was drawn from these studies. In contrast to a previous meta-analysis¹⁸, the result of this study indicated a higher incidence of halos with trifocal IOLs. The design of trifocal IOLs inherently leads to a loss of light transmission ranging from 18% to 20%, resulting in a relatively blurred image. Although such visual disturbances may hinder the widespread acceptance of trifocal IOLs, they were generally deemed acceptable in most studies, as the assessment of photopsia heavily relies on patients' subjective perceptions and tolerance¹⁷. Regarding subjective visual function questionnaires and visual quality. Additionally, the process of neuroadaptation and optical compromise are also significant factors. Therefore, the postoperative follow-up period is relevant in assessing how well patients adjust to the retinal image.

It was revealed that trifocal IOL demonstrated improved mean rank for near vision and intermediate vision, and a statistically significant difference was found while putting thread into needle and utility of mobile phone at p-values of 0.047 and 0.040, respectively. This study assessed intermediate vision by cooking, using a computer and the ability to see a speedometer without spectacles. Intermediate distance visual activities, such as operating machines, driving, working, etc., are essential daily. This result of the study agrees with the study of Bilbao-Calabuig R et al.¹⁰, which depicted that near and intermediate vision was improved with a Trifocal lens, a significant characteristic of Trifocal IOL over a monofocal lens. Rodov L 2019¹⁹. claimed that the Trifocal IOL most likely causes glare and halo photo disturbances. The frequent halo photic effect by the trifocal IOLs was due to the design properties, which inevitably reduce contrast sensitivity and generate photic effects¹⁷.

However, VA is not the only parameter used to assess the VR-QOL. VAs at all distances should be assessed before and after cataract surgery to evaluate the impact of treatment. This study evaluated VA at all distances before and after treating trifocal and EDOF IOLs. The visual acuity bilaterally after the surgery was assessed in EDOF and Trifocal groups, and significant improvement was observed with both IOLs. This result is congruent with the study of Webers VSE et al.²⁰ and Singh B 2020²¹, which compares visual outcomes after bilateral implantation with trifocal and EDOF IOLs.

While comparing patient satisfaction with the final surgical outcome, this study revealed that vision was improved by 100% with both treatment options of the Trifocal and EDOF group, and these results are comparable with the study of de Medeiros et al.¹⁴. Patients was satisfied with the final surgical outcome of both trifocal and EDOF IOLs **Figure II**. To bring the maximum visual benefits with surgical outcomes, we must familiarize ourselves with the characteristics of IOLs in real clinical settings. It depends on preoperative assessments, daily activities, economic status, and personalities.

The findings of this study indicate that trifocal intraocular lenses (IOLs) outperform EDOF IOLs in terms of near-distance vision. However, it should be noted that trifocal IOLs can lead to the occurrence of photic effects, such as halos. In clinical practice, it is essential to understand the characteristics of different IOLs to meet patients' expectations and ensure long-term satisfaction. Nevertheless, apart from considering IOL features, factors such as patients' personalities, expectations, preoperative conditions, and economic status should also be considered. It is recommended that more evidence-based publications and randomized controlled trials (RCTs) be

conducted to establish guidelines for IOL selection, aiming to maximize visual benefits and address individual visual requirements in the future.

Various limitations of this study should be documented, such as the small sample size. VR-QOL is not only influenced by VA. Hence, aberration, contrast sensitivity, dominant eye, cognitive function, depressive state, and stereoscopic vision of the patient must be evaluated in future with a larger sample size to assess the impact of cataract surgery assessment, which is not evaluated in this study.

CONCLUSION

VA was improved after implanting Trifocal and EDOF IOLs. Trifocal IOL demonstrated better performance at near & distant vision. The halo photic effect was generated more frequently by the trifocal IOLs. Patients were equally satisfied with the surgical outcome of both treatment options.

Ethics Statement: Bahawalpur Medical Dental College, Bahawalpur, IRB letter No. 03/2022. **Conflict of Interest:** The authors have no conflict of interest to declare

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Data Sharing Statement: The corresponding author can provide the data proving the findings of this study on request. Privacy or ethical restrictions bound us from sharing the data publically.

AUTHOR CONTRIBUTION Latif E: Proofreading Ijaz M: Writeup

Ali H: Literature search Ejaz A: Literature search Fatima K: Statistical analysis, writeup Chaudhary F: Data collection, tabulation, proofreading

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