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Indian Journal of Clinical and Experimental Ophthalmology

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Journal homepage: www.ijceo.org

Original Research Article

Visual outcome of cataract surgery by phacoemulsification in diabetic versus non-diabetic patients: A comparative study

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ARTICLE INFO

Article history: Received 08-01-2024 Accepted 13-04-2024 Available online 30-09-2024

Keywords:
Diabetic
Phacoemulsification
Best corrected visual acuity
Non diabetic

ABSTRACT

Aims: This study aims to evaluate and compare the results of phacoemulsification cataract surgery performed on diabetic patients with those of non-diabetic patients. The primary objective was to compare the visual outcome of phacoemulsification cataract surgery in diabetic patients and non-diabetic patients, and the secondary objective was to determine the final visual outcome following phacoemulsification cataract surgery in diabetics and non-diabetics.

Materials and Methods: A comparative study of the overall 300 eyes of the patients, in which 150 eyes were diabetic and 150 eyes were non-diabetic, underwent phacoemulsification cataract surgery with posterior chamber intra ocular lens implantation. Age, sex, follow-up, preoperative and postoperative best corrected visual acuity and post-operative complications were evaluated.

Results: Out of the 300 eyes of the patients, 150 eyes were diabetic and 150 eyes were non-diabetics. Phacoemulsification with posterior chamber intra ocular lens implantation was done in all patients. Follow up duration was 6 weeks. Postoperatively, 6 weeks after surgery, 31.7% of patients had BCVA of 6/9 or better in diabetic group while 36.3% of patients had BCVA of 6/9 or better in non-diabetic group. The difference in BCVA between two groups at postoperative 6 weeks was found to be statistically significant p value of <0.001. Post-operative complications included wound leak, striate keratopathy, folds in descemets membrane, corneal haze or edema, iritis, posterior capsular rent, cystoid macular edema, iridodialysis. The incidence was higher in the diabetic group as compared to non-diabetics.

Conclusion: Overall, the final visual outcome was better in non-diabetic group as compared to diabetic group. Diabetics are more likely to develop intra operative and postoperative complications. Thus, special care should be used both throughout the surgical procedure and the post-operative period.

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1. Introduction

Diabetes mellitus is a common disorder with a long history that is a major cause of blindness in the working age population. Although the retina is often believed to be the most typically damaged organ in this illness, other components of the visual system are also affected. After diabetic retinopathy, cataracts are the second most prevalent

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cause of blindness and have an elevated risk in this disease.

Diabetes is linked to both retinopathy and cataract development, with diabetics developing cataracts earlier than non-diabetics. ^{1,2}

India's urbanization-related lifestyle changes are having a negative impact on metabolism and contributing significantly to the country's rising diabetes patient population.^{3,4}

The duration of diabetes and the patient's age are other related factors. According to the International Diabetes

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Federation (IDF), 8.8% of adults have diabetes, with males having slightly higher rates (9.6%) than women (9%).⁵

Diabetes Mellitus prevalence in India has risen from 7.1% in 2009 to 8.9% in 2019. 6 Impaired glucose tolerance is predicted to affect 25.2 million individuals now, with a projected increase to 35.7 million by 2045. India is second in the world in terms of diabetes endemics, after China, with 77 million diabetics. Diabetic cataract is on the rise, as is the diabetic population. 6 Cataract is the second most prevalent visual problem associated with diabetes mellitus. One of the risk factors for cataract formation is diabetes mellitus. The percentage of diabetics with cataracts is about twothirds of diabetic population. Diabetes mellitus influences the function and morphology of the lens. Cataracts occur at an early age in diabetics compared to non- diabetics and 2-5 times more common in diabetic patients. ⁷ In India approximately 20% of all cataract surgery is done in diabetics.8

Therefore, an assessment of the outcomes of cataract surgery in diabetic patients is necessary due to the higher incidence of diabetes in developing nations like India. This study aims to evaluate and compare the results of cataract surgery performed on diabetic patients with non-diabetes.

2. Materials and Methods

The present case control study was done in the department of Ophthalmology of Krishna Institute of Medical Sciences, Krishna Vishwa Vidyapeeth Deemed to be University, Karad, Maharashtra from April 2022 to August 2023.

Out of 300 eyes of patients in which 150 eyes of diabetics and 150 eyes of Non diabetic Patients was taken by Convenience sampling method.

2.1. Inclusion criteria was given blow

- 1. Patients diagnosed with Type II and Type I diabetes mellitus
- 2. Age group 40-80 years.
- 3. Patient willing to undergo Phacoemulsification cataract surgery
- 4. Preoperative glycemic control with insulin, oral hypoglycemic, nutrition, or both.
- Phacoemulsification with divide and conquer technique which was done by single surgeon under peribulbar block was taken.

2.1.1. Exclusion criteria

- 1. Patients with traumatic or complicated cataract.
- 2. Neovascularization of iris.
- 3. Secondary glaucoma.
- 4. Diabetic Retinopathy
- 5. Uncontrolled diabetes.
- 6. Patient not willing to undergo cataract surgery

- 7. Cataract surgery combined with other surgeries such as glaucoma filtration surgeries or posterior segment surgeries.
- 8. Preoperative ocular co morbidity that would account for poor visual outcome, such as corneal opacity, pathological myopia, amblyopia, phacolytic glaucoma, phacomorphic glaucoma, pseudoexfoliation glaucoma, retinal vein occlusion, diabetic macular edema, macular hole, optic atrophy, or any ocular condition other than cataract hampering vision.

2.1.2. Pre-operative evaluation

Prior surgery, every patient was admitted to the hospital one day beforehand. Patients gave their consent after being fully informed about the study and receiving clearance from the institutional ethics committee. Every one of these patients had a pre-operative assessment and a full ocular examination, which included a detailed history regarding duration of diabetes, type, nature of treatment, associated systemic conditions were noted and the necessary demographic information. Additionally, a systemic examination was done. Ophthalmic examination included Best corrected visual acuity, Ocular evaluation was done with special regard to infective condition of the lid, adnexa, tear film abnormalities, keratopathy, and a routine gonioscopy was done in all patients to detect any neovascularization or other abnormalities was done with Slit lamp examination and grading of cataract gone according to LOCS III9 IOL calculation using SRK II/T, Hoffer Q formula, posterior segment evaluation using indirect ophthalmoscopy, B- scan in case of dense cataract and optical coherence tomography if required been done, Blood investigations: RBS, FBS, PPBS, HbA1c, HIV and HBsAg were done and Preoperative Refraction is useful to plan the IOL power necessary to obtain the postoperative refraction desired by the patient. A scan biometry along with Keratometry readings was used to calculate the appropriate IOL power been done.

In all patients Phacoemulsification cataract surgery with posterior chamber intra ocular lens implantation under peribulbar anaesthesia was done.

2.2. Phacoemulsification surgery technique

Under peribulbar local anaesthesia, each patient had phacoemulsification cataract surgery combined with posterior chamber intraocular lens (IOL) installation. One surgeon performed all of the procedures using the phaco machine (Zeiss Visalis 100). The conjunctival sac was infused with 5% povidone iodine for three minutes while proper sterilization procedures were followed. A 2.75 mm knife was used to make the primary corneal incision at 12 o'clock, and two additional 1.5 mm incisions were performed at 10 and 2 o'clock. Following phacoemulsification to remove the nucleus, the cortical

matter was removed using a two-way Simcoe cannula. The incisions were hydrated following the injection of an IOL. Because of the peribulbar anaesthesia, the eye was padded after the procedure and left open the following day.

2.3. Post-operative evaluation

Every patient underwent a thorough fundus and slit lamp examination on the first post-operative day. A visual acuity test was conducted. All patients were given corticosteroid and antibiotic combination eye drops six times a day at discharge; these were gradually reduced over the course of six weeks. If required tear substitutes hypersol were used. Following surgery, the patients were asked to review after on next day, two weeks and after six weeks. Patients had the fundus examination, visual acuity recording, and slit lamp examination at every follow up appointment. Patients had the fundus examination, slit lamp examination and visual acuity recording at every follow-up visit. Snellen's visual acuity chart was used to record the final visual result for statistical analysis.

2.4. Statistical analysis

SPSS software version 23 and Microsoft Excel were used to enter the data. To analyses all of the data, chi-square ($\chi 2$) test was used to determine if two categorical variables were related, and the Fisher exact test was used in cases where the cells' predicted count was less than 5. The means of the analysis variables were compared between the pre- and post-change in surgically induced astigmatism using the paired t test. When a p-value was less than 0.05, it was considered statistically significant at 95% confidence interval.

3. Results

The study group consists of 300 eyes in which 150 eyes of diabetics and 150 eyes of non-diabetics who underwent Phacoemulsification cataract surgery with posterior chamber intra ocular lens implantation under peri- bulbar anesthesia were included. In this study, in diabetic group 47(31.3%) were in the age group of 51-60 years, 88(55.3) were in the age group of 61-70 years and 20 (13.3%) were in the age group of 71-80 years. While in non-diabetic, 6 (4%) were in the age group of 40-50 years, 30 (20%) 51-60 years, 90(60%) 61-70 years and 24(16%) were in the age group of 71-80 years (Table 1). Majority of patients belonged to the age group of 61-70 years in both the groups.

Among diabetics 97 (64.7%) were males and 53 (35.3%) were females, while in non-diabetic, 84 (56%) were males and 66 (24%) were females (Table 2). Overall,181 males and 119 females participated in both diabetic and non-diabetic group. Majority of patients 86 (57.3%) were a known case of diabetes for period of 6-10 years. Only 10 (6.7%) patients were long-standing cases of diabetes for more than 10 years while on the other hand less than 5 years,

Table 1: Age groups in diabetic and non-diabetic group

Group	Age Group	Frequency	Percent
	51-60	47	31.3
Diabetic	61-70	83	55.3
group	71-80	20	13.3
	Total	150	100.0
	40-50	6	4.0
	51-60	30	20.0
Non diabetic	61-70	90	60.0
	71-80	24	16.0
	Total	150	100.0

54 (36%) were a known case of diabetes (Table 3)

Table 2: Distribution of gender between study groups

Group	Gender	Frequency	Percent
D:-14:-	Male	97	64.7
Diabetic	Female	53	35.3
group	Total	150	100.0
	Male	84	56.0
Non-diabetic	Female	66	44.0
	Total	150	100.0

Table 3: Duration of diabetes mellitus in diabetic group

Year	Frequency	Percent
0-5 Years	54	36.0
6-10 Year	86	57.3
More than 10 Years	10	6.7
Total	150	100.0

Table 4: Surgical complications status distribution in non-diabetic Groups

Non-diabetic gro	up	
No surgical complication	67	25.67%
Wound leak	4	1.53%
Striate keratopathy	15	5.75%
Subconjunctival haemorrhage	8	3.07%
Folds in descemets membrane	32	12.26%
Corneal haze or edema	46	17.62%
Iritis	54	20.69%
Descemets membrane detachment	5	1.92%
Posterior capsular rent	6	2.30%
Dispersed hyphema	13	4.98%
Intraoperative miosis	8	3.07%
Iris prolapse	3	1.15%
Cystoid macular edema	0	0.00%
Iridodialysis	0	0.00%

Post-operative inflammation including corneal haze or edema was the most common 70 (22.22%) complication in this group, followed by Iritis, indicative of inflammation in anterior chamber in 65 (20.63%) of the diabetic patients group. Striated keratopathy was found in 28 (8.89%),

Table 5: Surgical complication's status distribution of diabetic Group

Diabetic group		
No surgical complication	30	9.52%
Wound leak	4	1.27%
Striate keratopathy	28	8.89%
Subconjunctival haemorrhage	10	3.17%
Folds in descemets membrane	48	15.24%
Corneal haze or edema	70	22.22%
Iritis	65	20.63%
Descemets membrane detachment	9	2.86%
Posterior capsular rent	8	2.54%
Dispersed hyphema	19	6.03%
Intraoperative miosis	10	3.17%
Iris prolapse	6	1.90%
Cystoid macular edema	6	1.90%
Iridodialysis	2	0.63%

Iris Prolapse and Cysotic Macular Edema was found in 6 (1.90%) of diabetic patients. Corneal haze or edema suggestive of raised post-operative IOP was the most commonly found in diabetic group. On the other hand, post-operative inflammation (iritis) was most common complication 54(24.69%) in non-diabetic group, followed by folds in descemets membrane 32(12.26%) and corneal haze or edema 46 (17.62%) while no surgical complications were 67(25.67%) in non-diabetic group (Table 4)(Table 5).

On first post op day, 16.3% of patients had UCVA of 6/9 or better in diabetic group while 22% of patients had UCVA of 6/9 or better in non-diabetic group. The difference in UCVA between two groups at post op day 1 was found to be statistically significant with a Fisher Exact test value =14.72, p value of 0.008 (Table 6).

At two weeks after surgery, 24.7% of patients had UCVA of 6/9 or better in diabetic group while 25.7% of patients had UCVA of 6/9 or better in non-diabetic group. The difference in UCVA between two groups at post op two weeks was found to be statistically significant with a Fisher Exact test value =28.07, p value of <0.001. Majority of patients at two weeks having uncorrected visual acuity being less than 6/9 due to residual refractive error as a main cause for decreased uncorrected visual acuity in two weeks. (Table 7).

At 6 weeks after surgery, 31.7% of patients had BCVA of 6/9 or better in diabetic group while 36.3% of patients had BCVA of 6/9 or better in non-diabetic group. The difference in BCVA between two groups at post op 6 weeks was found to be statistically significant with a Fisher Exact test value =17.49, p value of <0.001(Table 8).

Final visual outcome in diabetic group was Good in 95 (31.7%), Borderline 35(11.7%), and Poor in 20(6.7%), whereas in non-diabetic group it was Good in 109 (36.3%), Borderline 34 (11.3%), and Poor in 7(2.3%) Best corrected

visual acuity at post-operative 2 weeks and after 6 weeks was better in non-diabetic group as compared to diabetic group and this was found to be statistically significant (p-value 0.02), Fisher exact test value 7.26 (Figure 1).

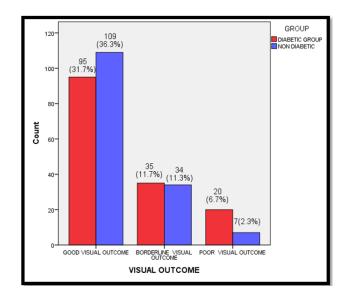


Figure 1: Showing final visual outcome

4. Discussion

In this study, the highest number of patients were in the age group of 61-70 years that is in diabetic 83 (55.3%) & 90 (60%) in non-diabetic group. This correlates with a study done by Kahn HA ¹⁰ which states that cataract incidence is under 65 years of age or contradictory to Sowmya C A ¹¹ found the highest number of patients in age group of 51-60 years. Age-related cataract is a bilateral disorder, with one eye affected first. ¹⁰

Among diabetics 97 (64.7%) were males and 53 (35.3%) were females, while in non-diabetic, 84 (56%) were males and 66 (24%) were females contradictory to Sowmya C A¹¹ in which female are more affected.

One method for achieving preoperative glycemic control was the use of insulin. Oral hypoglycemic medications (OHAs) or a combination of the two. Most of the patients had been given a type 2 diabetes diagnosis and were receiving OHAs as therapy. Regular insulin was administered in supplementary doses when plasma glucose levels above 300 mg/dl. Appropriate glycaemic control was attained by adjusting the insulin dosage in accordance with the plasma glucose levels. In this study, Majority of patients 86 (57.3%) were a known case of diabetes for period of 6-10 years. Only 10 (6.7%) patients were long-standing cases of diabetes for more than 10 years. The duration of diabetes is an important risk factor in the pathogenic of diabetic cataract. ¹²

Table 6: Showing post-operative uncorrected visual acuity -1 Day comparison between diabetic and non-diabetic group

UCVA post op day 1		Group		Total	Fisher Exact	
	•	Diabetic	Non-diabetic	Total	test value	p-value
6/6-6/9	Count	49	66	115		
0/0-0/9	% of Total	16.3%	22.0%	38.3%		
6/12-6/18	Count	57	52	109		
0/12-0/18	% of Total	19.0%	17.3%	36.3%		
6/24-6/36	Count	20	12	32		
0/24-0/30	% of Total	6.7%	4.0%	10.7%		
6/60-5/60	Count	20	12	32	14.72	0.008
6/60-5/60	% of Total	6.7%	4.0%	10.7%		
4/60-3/60	Count	1	8	9		
	% of Total	0.3%	2.7%	3.0%		
-2/60	Count	3	0	3		
<2/60	% of Total	1.0%	0.0%	1.0%		
TD . 1	Count	150	150	300		
Total	% of Total	50.0%	50.0%	100.0%		

Table 7: Showing post-operative uncorrected visual acuity -2 weeks

David On LICXA	2 Washa	Group		Total	Fisher Exact test value	p-value
Post Op UCVA 2 Weeks		Diabetic	Non-diabetic	iotai		
(16, 610	Count	74	77	151		
6/6-6/9	% of Total	24.7%	25.7%	50.3%		
6/10 6/10	Count	45	53	98		
6/12-6/18	% of Total	15.0%	17.7%	32.7%		
6124 6126	Count	20	0	20		
6/24-6/36	% of Total	6.7%	0.0%	6.7%	28.07	< 0.001
6160 5160	Count	9	18	27		
6/60-5/60	% of Total	3.0%	6.0%	9.0%		
4/60-3/60	Count	2	2	4		
4/00-3/00	% of Total	0.7%	0.7%	1.3%		
Total	Count	150	150	300		
Total	% of Total	50.0%	50.0%	100.0%		

Table 8: Showing post-operative best corrected visual acuity — 6 weeks

Post OP BCVA 6 weeks		Group		m 4 1	Fisher Exact	
		Diabetic	Non-Diabetic	Total	test value	p-value
6/6-6/9	Count	95	109	204		
0/0-0/9	% of Total	31.7%	36.3%	68.0%		
6/12-6/18	Count	35	34	69		<0.001
0/12-0/18	% of Total	11.7%	11.3%	23.0%		
(124 (126	Count	18	2	20	17.49	
6/24-6/36	% of Total	6.0%	0.7%	6.7%		
6160 5160	Count	0	3	3	•	
6/60-5/60	% of Total	0.0%	1.0%	1.0%		
4/60 2/60	Count	2	2	4		
4/60-3/60	% of Total	0.7%	0.7%	1.3%		
Total	Count	150	150	300		
	% of Total	50.0%	50.0%	100.0%		

All patients who had cataract surgery received local anaesthesia. Cataract surgery under local anaesthesia improves metabolic management in diabetic patients. Its usage preserves glucose haemostasis and eliminates the rise in cortisol and glucose found under general anaesthesia, as well as eliminating the requirement for post-operative fasting. ¹³

Most common intraoperative complication occur in diabetic group was 'intraoperative Miosis' occurring in 10(3.17%) of patients as compared to 8(3.07%) in nondiabetic group. Kutschan A et al. 14 found insufficient pupil dilation was the most common intraoperative complication in diabetics. Zaczek A et al. 15 studied the pupil size in patients with diabetes mellitus during cataract surgery and concluded that constriction during surgery is more pronounced in diabetic eyes as compared to non-diabetics. The entire surgical procedure took longer in diabetics due to ineffective mydriasis. A posterior capsular rent was seen in 8 (2.54%) of 10(3.17%) diabetic individuals with intraoperative Miosis. Sub-conjunctival hemorrhage occurred in 10 (3.17%) diabetic and 8(3.07%) non-diabetic patients. Posterior capsular rent occurred in 8(2.54%) diabetic patients. This is higher as compared to its incidence in non-diabetics where posterior capsular rent occurred in 6 (2.30%) of patients. Higher incidence of Posterior capsular rent due to intraoperative miosis in diabetics. Corneal haze or edema was the most common post-operative in 70 (22.22%) diabetic groups and Iritis 54(20.69%) in nondiabetics group. Folds of descemets membrane were seen in 48(15.24%) diabetics and 32(12.2%) non diabetics. Striate keratopathy was seen in 28(8.89%) diabetics and 15(5.75%) non-diabetics. Diabetes, according to Larsson et al., ¹⁶ is related with structural changes in corneal endothelial cells such as polymegathism and pleomorphism. The cornea of diabetes individuals has been observed to be thicker than that of non-diabetic persons. 17 Cataract removal and IOL insertion induce damage to the already compromised corneal endothelium, resulting in corneal swelling or edema. As a result, as compared to non-diabetic patients, diabetes patients' eyes revealed higher damage in corneal endothelial cells following cataract surgery, as well as a delay in the post-operative recovery of corneal edema. There was a higher proportion of intraoperative and postoperative complications documented in the diabetic group.

Diabetes reduces corneal sensitivity, and high levels of stress can cause keratoepitheliopathy. ¹⁸ In diabetic cornea, decreased expression of entactin/laminin 66-1 and 10 as well as their binding alpha-3-beta integrin may significantly affect the adhesive and migratory characteristics of corneal epithelial cells. This change in corneal cell-BM adhesion might be the mechanism behind clinically reported problems in epithelial barrier function, adhesion, epithelial integrity, and wound healing. ¹⁹ Raised post-operative IOP also correlates to an increase in post-operative corneal

edema. Bleeding in anterior chamber in the form of dispersed RBC'S occurred in 19 (6.03%) diabetics and 13 (4.98%) non-diabetics. Bleeding is common in diabetes due to fragility of iris microvasculature and arteriosclerotic changes in vessel wall. Menchini U et al. ²⁰ showed an increased risk of ocular complication in diabetes after cataract surgery but modern surgical techniques have minimized them, leading to overall good visual outcome. Kutschan A et al. ¹⁴ in study said, among early postoperative complications, anterior segment inflammation was common complication.

In this study cystoid macular edema is seen in 6 (1.90%) diabetic and there is no patient in non-diabetic group. In diabetics with or without evidence of diabetic retinopathy the blood aqueous barrier is impaired, it leads to inflammation and development of a cystoid macular edema, a process that is exacerbated by cataract surgery. ²¹

Long standing diabetes is associated with changes in the cornea, Lids and conjunctiva such as dryness, surface abnormalities which might alter the refractive status in addition to this they have susceptibility to alter blood ocular barrier which might interfere just like iritis, postoperative inflammation in presence of macular edema

Stratsman BR et al. 22 said when eyes with diabetic retinopathy or other pre-existing ophthalmic diseases responsible for decreased vision were excluded, postoperative visual acuity of 6/12 or better was obtained in 93% of diabetic eyes and 96% of non-diabetic eyes. In our study, Final visual outcome in diabetic group was Good in 95 (31.7%), Borderline 35(11.7%), and Poor in 20(6.7%), whereas in non-diabetic group it was Good in 109 (36.3%), Borderline 34 (11.3%), and Poor in 7(2.3%) Best corrected visual acuity at 6 weeks was better in non-diabetic group as compared to diabetic group and final visual outcome was found to be statistically significant (p-value 0.02), fisher exact test value 7.26. Overall, the final visual outcome was better in non-diabetics group as compared to diabetic group. Similar study done by Raj Kumar Gupta et al. 23 consisting of 50 diabetics and 50 non- diabetics, the post-surgical visual acuity in the diabetic and non-diabetic group was found to be good respectively at 6 weeks post-op.

5. Conclusion

Three hundred patients who underwent phacoemulsification were evaluated in this study. One hundred fifty patients of which were diabetes and one hundred fifty patients of non-diabetes. Diabetes mellitus is a risk factor for development of age related cataract. A comprehensive ocular examination goes a long way in preoperative evaluation of patients especially in diabetes. Pre-operative preparation including mydriasis is a crucial determinant of the final outcome of cataract surgery. Local anesthesia with peribulbar-block is the anaesthesia of choice in diabetic patients for cataract surgery. In our study, Most common intraoperative

complication occur in diabetic group was 'intraoperative Miosis' occurring in 10(3.17%) of patients as compared to 8(3.07%) in non-diabetic group. Corneal Haze or edema was more frequent complication in diabetics. Final visual outcome in diabetic group was Good in 95 (31.7%), Borderline 35(11.7%), and Poor in 20(6.7%), whereas in non-diabetic group it was Good in 109 (36.3%), Borderline 34 (11.3%), and Poor in 7(2.3%) Best corrected visual acuity at 6 weeks was better in non-diabetic group as compared to diabetic group and final visual outcome was found to be statistically significant (p-value 0.02), Fisher exact test value 7.26. Overall, the final visual outcome was better in non-diabetics group as compared to diabetic group. There was a higher proportion of intraoperative and postoperative complications documented in the diabetic group.

6. Limitation of the Study

This study's limitations were a limited sample size and a brief follow-up period is needed along with Type I-II Diabetes Mellitus patients were not differentiated, Secular Microscopy evaluation was not done which was needed for the study.

7. Abbreviations

BCVA: Best corrected visual acuity, UCVA: Uncorrected visual acuity, IHD: Ischemic heart diseases, CKD: Chronic kidney diseases, BA: Bronchial asthma, BEP: Benign enlargement of prostate, HTN: Hypertension, COPD: Chronic enlargement of Obstructive Diseases, PSC: Posterior Sub capsular Cataract, NS: Nuclear Sclerosis, LOCS: Lens opacification classification system, RBS: Random blood sugar, PPBS: Post prandial Blood sugar, HIV: Human immunodeficiency virus, HbsAG: Hepatitis B Surface Antigen, IOL: Intraocular lens implantation, IDF: Indian Diabetes Federation, HbA1c: Glycated hemoglobin

8. Source of Funding

None.

9. Conflict of Interest

None.

10. Ethical Statement

The study got permission for data collection at Krishna Institute of Medical Sciences and its ethical clearance from the ethical committee of Krishna Vishwa Vidyapeeth Deemed to be University, Karad, Maharashtra.

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Cite this article: V Naik S, S Joshi B. Visual outcome of cataract surgery by phacoemulsification in diabetic versus non-diabetic patients: A comparative study. *Indian J Clin Exp Ophthalmol* 2024;10(3):532-539.