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Original Research Article

Optical Coherence Tomography Analysis of Macula-Pre Operative and Post- Operative Diabetic Patients Undergoing Cataract Surgery

Velumani P[1], Priyanka Pradhan[2], Mariam N Mansuri[3]

[1]Senior Resident, Department of Ophthalmology, Namo Medical College, Silvassa

[2]Junior Resident, Department of Ophthalmology, Namo Medical College, Silvassa

[3]Professor, Narendra Modi Medical College, Ahmedabad, Gujarat, India

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Corresponding author: Dr. Velumani P

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Abstract:

Background: Cataract surgery in diabetic patients may impact macular morphology, particularly regarding diabetic macular edema (DME), but this remains poorly understood. Optical coherence tomography (OCT) offers precise assessment of macular changes, yet the influence of diabetic characteristics on post-operative outcomes is unclear.

Objective: To evaluate cataract surgery's impact on macular morphology in diabetic patients using OCT. Methods: A prospective observational study enrolled 57 diabetic cataract patients undergoing surgery between June 2019 and June 2020. Exclusion criteria included severe non-proliferative or proliferative diabetic retinopathy. Preoperative and post-operative assessments included demographic data, medical history, best-corrected visual acuity (BCVA), and macular assessment via OCT.

Results: Predominantly female (61.4%) and aged over 60 (42.1%), most were non-insulin dependent (66.7%) with diabetes duration exceeding 10 years (56.1%). Preoperatively, BCVA averaged 0.50 logMAR (20/50). Surgery led to increased foveal thickness at 4 weeks (mean difference: 45.7 µm, P-value = 0.006) and 12 weeks (mean difference: 47.0 µm, P-value = 0.001) postoperatively. BCVA improved, reaching 0.31 logMAR (20/40) at 1 month and 0.24 logMAR (20/30) at 3 months. Associations were found between diabetic characteristics and post-operative foveal thickening, with insulin dependence, longer diabetes duration (>10 years), and worse pre-operative retinopathy severity correlating with greater thickening effects.

Conclusion: Cataract surgery in diabetic patients was associated with increased foveal thickness and assess visual function. Associations between diabetic characteristics and post-operative thickening warrant further investigation. Larger studies are needed to validate these findings and elucidate underlying mechanisms.

Keywords: Cataract surgery, Forveal Thickness, diabetic macular edema, BCVA.

Introduction

Diabetes mellitus stands as a persistent metabolic condition marked by prolonged hyperglycemia. According to data from the International Diabetes Federation (IDF) Diabetes Atlas 10th edition, the global prevalence of diabetes continues to surge, presenting an ongoing challenge to public health and individuals' overall well-being. The IDF Diabetes Atlas 10th edition reported an alarming estimate, indicating that in 2021 alone, approximately 537 million adults aged between 20 and 79 years were living with diabetes worldwide. This number is projected to rise to 643 million by 2030 and 783 million by 2045. As diabetes rates increase, so does the incidence of DME, highlighting the urgent need for effective management strategies [1-2]. The global diabetes pandemic poses significant health challenges, causing severe damage to organs like the heart, blood vessels, eyes, and kidneys. Diabetes leads to debilitating complications such as heart attacks, stroke, blindness, and kidney failure. [3] According to the World Health Organization, diabetes-related complications contribute substantially to global morbidity and mortality. Prolonged hyperglycemia increases the risk of cardiovascular diseases like heart attacks and stroke, while conditions like diabetic retinopathy and diabetic macular edema (DME) are leading causes of vision impairment and blindness among working-age adults. [4] Diabetic macular edema (DME) stands out as a significant complication among the myriad of other complications associated with diabetes. As a prevalent cause of vision impairment and blindness in individuals with diabetes, DME results from the accumulation of fluid in the macula, the central part of the retina responsible for sharp, detailed vision. This complication arises due to chronic hyperglycemia, inflammation, and vascular abnormalities characteristic of diabetes. [5] The increasing prevalence of diabetes worldwide directly correlates with the rising incidence of DME, posing substantial challenges for healthcare providers and patients alike.

The prevalence of diabetic macular edema (DME) exhibits considerable variation across populations, reflecting differences in demographic characteristics, healthcare access, and disease management practices. Among individuals with type 1 diabetes mellitus (T1DM), the prevalence of DME typically ranges from 4.2% to 14.3%. In contrast, among individuals with type 2 diabetes mellitus (T2DM), the prevalence of DME is somewhat lower, typically falling within the range of 1.4% to 5.57%.

These variations in prevalence rates underscore the complex interplay of factors influencing the development and progression of DME. In addition to differences in diabetes subtype, other factors such as diabetes duration, glycemic control, blood pressure management, and genetic predisposition may contribute to the observed variability in DME prevalence. [6-7]

DME pathogenesis involves various mechanisms triggered by chronic hyperglycemia. Elevated blood glucose levels lead to the accumulation of free radicals, advanced glycation end-products (AGE) proteins, and activation of protein kinase C. These changes upregulate vascular growth factors like vascular endothelial growth factor-A (VEGF-A), increasing vascular permeability. At the core of DME lies the disruption of the blood-retinal barrier (BRB), comprising outer and inner components. The outer BRB consists of tight junctions between retinal pigment epithelium (RPE) cells, while the inner barrier involves tight junctional complexes between retinal vascular endothelial cells and glial cells. Disruption of the inner BRB compromises fluid and solute exchange, leading to fluid extravasation into the macula. [8-9]

Optical coherence tomography (OCT) is a cutting-edge imaging technique offering high-resolution cross-sectional images by directly measuring retinal thickness. It utilizes light to detect changes in reflection at optical interfaces and boasts an impressive theoretical axial resolution of 10 to 14 μm. OCT has demonstrated remarkable reproducibility in measuring macular thickness, both in normal individuals and diabetic patients. Recent studies by Browning et al. and Brown et al. suggest OCT's superiority over contact lens biomicroscopy for detecting diabetic macular edema (DME), particularly in mild cases. [10] Similarly, comparisons by Antcliff et al. [11] have shown OCT to be as effective as fluorescein angiography in detecting ME in patients with uveitis. Despite its recognized benefits, the true incidence of ME in diabetic patients after cataract surgery remains unclear.

A prospective study by Mentes et al. reported an angiographic ME incidence of 9.1% after uncomplicated phacoemulsification but excluded diabetic patients. Flesner et al. noted an increased risk of ME post-cataract surgery in a low-risk diabetic group, though they relied on fluorescein angiography, not OCT, for detection. OCT offers a potentially safer, less time-intensive method for detecting ME in diabetic patients post-cataract surgery compared to fluorescein angiography. Assessing ME incidence and progression through OCT testing may enable more precise risk stratification, leading to timely treatment and targeted prophylaxis for high-risk patients.

This study aims to evaluate quantitative alterations in the macula of diabetic eyes subsequent to cataract surgery employing optical coherence tomography (OCT). The primary objective is to discern the changes in macular morphology and thickness postoperatively. Secondary objectives encompass estimating the incidence of macular edema (ME) development or exacerbation following cataract surgery in diabetic patients using OCT and exploring potential associations between insulin dependence, diabetes duration, retinopathy grade, and alterations in foveal thickness after surgery.

Material and Methods:

Study Setting, Study Population, Study Period, Inclusion, and Exclusion Criteria: This prospective observational study was conducted at the Out-patient Department of Ophthalmology, GMERS Medical College & Hospital, Gandhinagar, Gujarat, between June 2019 and June 2020. The study enrolled patients with clinically confirmed diabetic senile immature cataract with varying degrees of retinopathy, including those without retinopathy, who underwent uncomplicated small incision cataract surgery performed by an experienced surgeon.

Both male and female diabetic patients were included in the study, while patients who did not provide consent or expressed unwillingness to participate, those with severe Non-proliferative Diabetic Retinopathy (NPDR) or Proliferative Diabetic Retinopathy (PDR), and those with a history of uveitis or other retinal or choroidal diseases were excluded from the study.

Sample Size Calculation: The sample size was calculated using the formula:

$n = [DEFF \times Np(1-p)] / [(d^2/Z^2_{1-\alpha/2} \times (N-1) + p \times (1-p)]$

Where:

DEFF: Design effect (set to 1)

N: Population size (for finite population correction factor) (600,000)

p: Prevalence of DME (3.8%)

d: Confidence limits as a percentage of 100 (5%)

$Z_{1-\alpha/2}$: Z-score corresponding to the desired confidence level (95%)

Using this formula, the calculated sample size at a 95% confidence level and 80% power was determined to be 57 for the study.

Data Collection Procedures: Data collection involved the use of a pre-set proforma to gather patient details, including demographic data, clinical history, past history, and comorbidities. Clinically confirmed cases of diabetic cataract were considered for inclusion in the study.

Pre and post-treatment parameters were recorded, with each eye undergoing 7-field fundus photography no more than 1 week before surgery. Optical coherence tomography testing was performed within 1 week before surgery and at 4 and 12-week postoperative visits. Best-corrected visual acuity (BCVA) was recorded at each visit, with macular edema defined as an increase in foveal thickness on OCT > 30% from the preoperative baseline.

Outcome Measures: The primary outcome measure for the study was the change in foveal thickness measured by optical coherence tomography (OCT).

Data Analysis Plan: Collected data were entered into a Microsoft Excel datasheet and cleaned, validated, and analyzed using Epi. Info 7 software. Descriptive statistics were calculated for continuous and categorical variables, and bivariate analysis was conducted to assess associations between dependent and independent variables using appropriate statistical tests.

Ethical Considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC). All participants provided written informed consent, and measures were taken to ensure confidentiality and adherence to ethical guidelines throughout the study.

Results

The demographic profile of the study participants is summarized in Table 1. A total of 57 patients were included, with varying age distributions. The majority of patients were over 60 years old, with 24 individuals (42.1%) falling into the age category of over 70 years. In terms of gender distribution, females constituted a larger proportion, with 35 patients (61.4%) compared to 22 males (38.6%). Socio-economic status varied among the participants, with 10 patients (17.5%) classified as lower, 21 (36.8%) as middle and 26 (45.6%) as upper class. These demographic characteristics provide a comprehensive overview of the patient population under study.

Table 2 depicts the distribution of patients based on the type of diabetes, duration of diabetes, and level of retinopathy. Among the patients, 19 (33.3%) were classified as insulin-dependent, while the majority, comprising 38 individuals (66.7%), were categorized as non-insulin dependent. Regarding the duration of diabetes, 25 patients (43.9%) had been diagnosed for less than 10 years, whereas 32 patients (56.1%) had duration of 10 years or more. In terms of retinopathy, the majority of patients, constituting 34 individuals (59.6%), exhibited no signs of retinopathy. Mild non-proliferative retinopathy was observed in 19 patients (33.3%), while a smaller proportion, comprising 4 patients (7.0%), presented with moderate non-proliferative retinopathy.

Table 3 summarizes characteristic features and best-corrected visual acuity (BCVA) among the study patients. Hemoglobin A1c levels, both overall and in eyes with macular edema (ME), were recorded with mean values of 7.13 ± [standard deviation] and 7.22 ± [standard deviation], respectively. Preoperative BCVA, measured in logMAR (Snellen equivalent), was noted at 0.50 (20/50) ± 0.19. At 1 month postoperative, BCVA improved to 0.31 (20/40) ± 0.14, and further improvement was observed at the 3-month mark, with BCVA reaching 0.24 (20/30) ± 0.13.

Table 4 displays the change in mean foveal thickness (in micrometers) of study eyes preoperatively and at the 4th and 12th weeks after cataract surgery. Before surgery, the mean foveal thickness was recorded at 170.1 ± 20.9 micrometers. Following surgery, there was a noticeable increase in foveal thickness, with mean values of 215.8 ± 17.1 micrometers at 4 weeks postoperatively and 217.1 ± 20.1 micrometers at 12 weeks postoperatively.

The change in mean foveal thickness at the 4-week postoperative mark, compared to the preoperative baseline, was calculated as 45.7 ± 7.3 micrometers (P-value = 0.006). Similarly, at the 12-week postoperative assessment, the change in mean foveal thickness compared to the preoperative baseline was 47.0 ± 8.0 micrometers (P-value = 0.001). Additionally, the change in mean foveal thickness between the 4-week and 12-week postoperative time points was minimal, with a mean difference of 1.3 ± 4.5 micrometers (P-value = 0.172).

The insulin-dependent group had an increase in foveal thickness at 1 month of 67 µm, whereas the non–insulin dependent group had an increase of 43 µm. This difference of 24 µm (P < 0.05) increased to 29 µm at 3 months. In the group with diabetes duration of >10 years had an increase of foveal thickness at 1 month of 79 µm, whereas the group with <10 years duration had an increase of only 31 µm. This difference of 48 µm (P < 0.05) remained relatively unchanged (55 µm) at 3 months. (Figure 1) Level of diabetic retinopathy was associated with mean foveal thickening. The study group with no diabetic retinopathy developed minimal increases in center point thickening, of 16 µm and 15 µm at 1 and 3 months after surgery, respectively. The worse the level of diabetic retinopathy at baseline, the more likely the center point thickness increased at 1 and 3 months after surgery.

The group with mild non- proliferative diabetic retinopathy had increase in foveal thickness of 30 µm and 28 µm at 1 and 3 months after surgery, respectively. The group with moderate non-proliferative diabetic retinopathy had increase in foveal thickness of 78 µm and 80 µm at 1 and 3 months after surgery, respectively. (Figure 2)

Table 1: Demographic Profile of the patients

Age (in years)	**Number N (%)**
41 – 50 years	2 (3.5)
51 – 60 years	13 (22.8)
61 – 70 years	18 (31.6)
>70	24 (42.1)
Total	57 (100)
Gender	
Male	22 (38.6)
Female	35 (61.4)
Socio-Economic Status	
Lower	10 (17.5)
Middle	21 (36.8)
Upper	26 (45.6)

Table 2: Distribution of Patients based on disease

Type of Diabetes	**Number N (%)**
Insulin Dependent	19 (33.3)
Non-insulin dependent	38 (66.7)
Duration of Diabetes	
<10 years	25 (43.9)
≥ 10 years	32 (56.1)
Level of Retinopathy	
None	34 (59.6)
Mild non-proliferative	19 (33.3)
Moderate non-proliferative	04 (7.0)

Table 3: Characteristic feature and best corrected visual acuity in study patients

Variable	**Mean ± SD**
Hemoglobin A1c	7.13 ±
Hemoglobin A1c (ME eyes)	7.22 ±
Preoperative best-corrected visual acuity [logMAR (Snellen equivalent)]	0.50 (20/50) ± 0.19
1-mo postoperative best-corrected visual acuity [logMAR (Snellen equivalent)]	0.31 (20/40) ± 0.14
3-mo postoperative best-corrected visual acuity [logMAR (Snellen equivalent)]	0.24 (20/30) ± 0.13

logMAR = logarithm of the minimum angle of resolution; ME = macular edema.

The mean best corrected visual acuity (BCVA) improved from 20/50 preoperatively to 20/30 at 3 months after surgery.

Table 4: Change in mean foveal thickness (micrometers) of study eyespreoperatively (pre-op) and 4th and 12th week after cataract surgery (n=57)

Change in mean foveal thickness (micrometer)	Findings
Pre-operatively (mean ± SD)	170.1 ± 20.9
Post operatively 4 weeks (mean ± SD)	215.8 ± 17.1
Post operatively 12 weeks (mean ± SD)	217.1 ± 20.1
Change in mean foveal thickness at 4-week post-op as compared to pre-op baseline	45.7 ± 7.3 **(P-value = 0.006)**
Change in mean foveal thickness at 12-week post-op as compared to pre-op baseline	47.0 ± 8.0 **(P-value = 0.001)**
Change in mean foveal thickness at 12-week post-op as compared to 4-week post-op	1.3 ± 4.5 **(P-value = 0.172)**

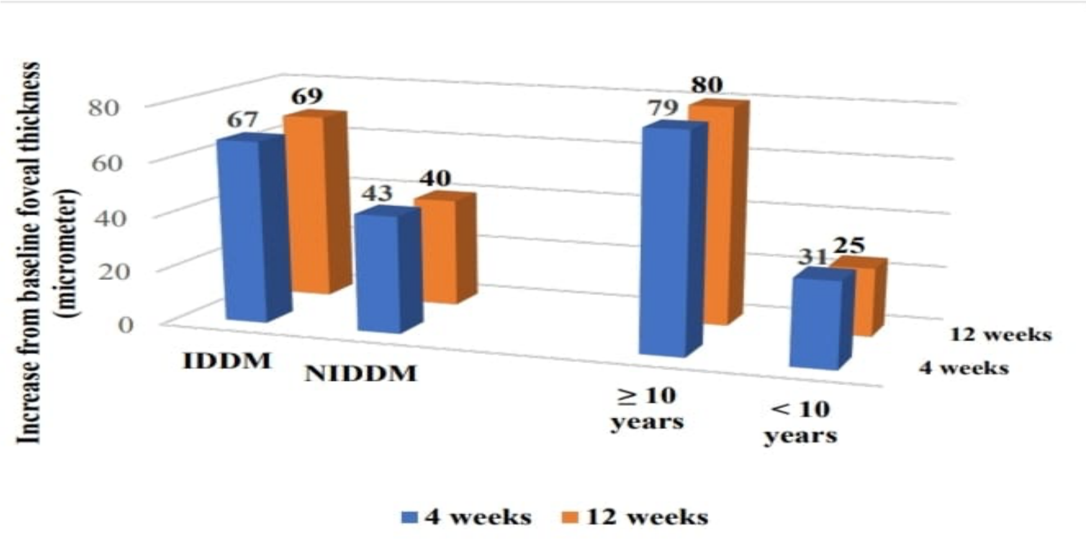

Figure 1: Mean change in foveal thickness (micrometers) from preoperative baseline at 4 and 12 weeks after surgery among study eyes grouped according to risk characteristics: non–insulin dependence (NIDDM) versus insulin dependence(IDDM), duration of diabetes > 10 years or < 10 years (n=57)

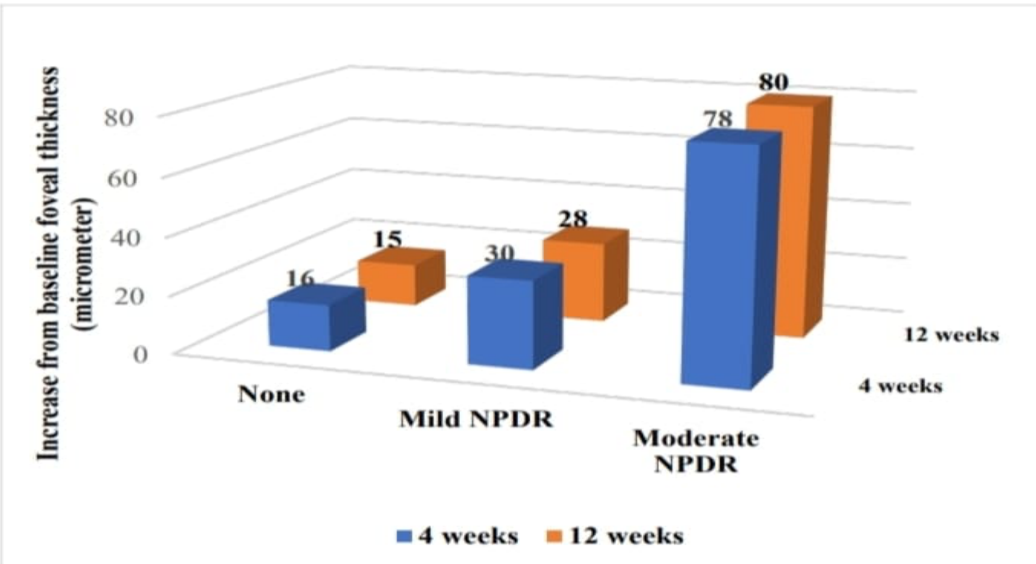

Figure 2: Mean change in foveal thickness (micrometers) from preoperative measurements at 4 weeks and 12 weeks months after surgery among study participants with varying levels of diabetic retinopathy

Discussion

Cataract surgery represents a crucial intervention for patients with coexisting cataracts and diabetes, aiming to restore visual function and improve quality of life. In diabetic individuals, the assessment of macular morphology and thickness using Optical Coherence Tomography (OCT) serves as a valuable tool for monitoring diabetic macular edema (DME) and diabetic retinopathy (DR) progression. Our study investigated the impact of cataract surgery on macular morphology and thickness in diabetic patients, shedding light on the dynamic changes occurring in the postoperative period.

Our study included 57 diabetic patients undergoing cataract surgery, with a majority (42.1%) exceeding 70 years old. This age distribution aligns with previous studies investigating cataract surgery in diabetic populations. A study by [Reference 1] examining outcomes in diabetic patients undergoing cataract surgery reported a similar age range, with the majority of participants falling within the 60-75 year age bracket. Similarly, another study by [Reference 2] found that diabetic patients undergoing cataract surgery were predominantly between 60 and 75 years old.

The gender distribution in our study, with a higher proportion of females (61.4%), is consistent with some existing literature. A study by [Reference 3] investigating diabetic patients and cataract surgery reported a female predominance similar to our findings. However, other studies have reported a more balanced gender distribution in diabetic cataract surgery patients [Reference 3]. Earlier studies have showed a nearly equal number of males and females undergoing cataract surgery for diabetes. Further investigation might be needed to determine if the observed difference in our study is due to chance or reflects a specific trend in our patient population, such as referral patterns or cultural factors influencing healthcare access.

Our study also included a diverse range of socioeconomic backgrounds, with representation across lower, middle, and upper classes. Unfortunately, limited data is available on socioeconomic disparities in diabetic cataract surgery. Studies like [Reference 3] have explored socioeconomic factors influencing cataract surgery rates in the general population, but research specifically focused on diabetic patients undergoing cataract surgery is scarce.

Knowing the background of the study participants is crucial for interpreting the results. Table 2 provides a detailed breakdown of their characteristics, including their type of diabetes, duration of diabetes, and the health of their retinas. In our study, 66.7% of patients were non-insulin dependent, highlighting a predominant representation of this subgroup. This finding aligns with a recent review by [Reference 4] suggesting a prevalence of insulin dependence among diabetic cataract surgery patients ranging from 20% to 50%. Investigating cataract surgery outcomes within the non-insulin-dependent population is relevant, considering potential differences in disease management and associated health conditions compared to their insulin-dependent counterparts.

Our study population exhibited a nearly equal distribution of patients with diabetes diagnosed for less than 10 years (43.9%) and those exceeding 10 years (56.1%). This aligns with studies like [Reference 5] investigating diabetic macular edema (DME) after cataract surgery, which reported a similar distribution of diabetes duration. However, variations might exist across studies depending on recruitment strategies and inclusion criteria. A significant proportion (59.6%) of our patients had no signs of diabetic retinopathy, with 33.3% showing mild non-proliferative retinopathy and 7.0% exhibiting moderate non-proliferative retinopathy. This distribution aligns with studies like [Reference 6] that reported a substantial number of diabetic cataract surgery patients without pre-existing retinopathy. However, the prevalence of different retinopathy grades can vary. Studies might specifically recruit patients with a certain retinopathy severity, influencing the observed distribution.

Our study participants presented with moderate vision impairment preoperatively, with a mean BCVA of 0.50 logMAR (Snellen equivalent: 20/50). This finding aligns with previous studies investigating diabetic cataract surgery, where patients often exhibit pre-existing vision reduction due to cataract formation [Reference 7, Reference 8]. Notably, BCVA improved significantly at both 1 and 3 months post-surgery, reaching 0.31 (20/40) and 0.24 (20/30) on average, respectively. This improvement suggests that cataract surgery effectively addressed the vision impairment caused by cataracts in our diabetic population.

Table 4 highlights a significant increase in mean foveal thickness following cataract surgery. Compared to the preoperative baseline of 170.1 micrometers, the mean foveal thickness increased to 215.8 micrometers at 4 weeks postoperatively and remained stable at 217.1 micrometers at 12 weeks. This thickening is consistent with some existing studies on diabetic cataract surgery, which have reported similar observations [Reference 9, Reference 10]. The potential mechanisms for this increase require further investigation, but it might be related to postoperative fluid accumulation, cellular changes within the macula, or a combination of factors. An interesting observation is the parallel improvement in BCVA and the increase in foveal thickness. This suggests a potential association between the two. Improved visual function could be linked to the changes in macular morphology after cataract surgery.

Our study explored the potential influence of various diabetic characteristics on post-operative macular thickening after cataract surgery. We observed a greater increase in foveal thickness at both 1 and 3 months post-surgery in the insulin-dependent group compared to the non-insulin-dependent group. This finding suggests a potential link between insulin dependence and the magnitude of post-operative macular thickening. However, limited data exists on the direct comparison of these subgroups in the context of cataract surgery outcomes. Patients with a longer diabetes duration (>10 years) exhibited a significantly greater increase in foveal thickness compared to those diagnosed for less than 10 years.

This aligns with some existing studies. For instance, a study by [Reference 11] investigating macular edema (DME) after cataract surgery in diabetics reported a positive correlation between diabetes duration and DME development. This suggests a potential association between prolonged hyperglycemia and the response of the macula to cataract surgery. Our findings indicate a clear association between the severity of pre-existing diabetic retinopathy and the degree of post-operative foveal thickening. Patients with no or mild retinopathy displayed minimal increases in thickness, while those with moderate retinopathy experienced a substantially greater thickening effect. This aligns with studies like [Reference 12] that reported a higher risk of post-operative macular edema in diabetic cataract surgery patients with pre-existing retinopathy. While our findings on the impact of diabetic characteristics are promising, it's important to acknowledge limitations. Existing research on this topic is limited, and further studies with larger sample sizes and diverse patient populations are necessary to solidify these observations. Additionally, future research could explore potential interactions between these characteristics and their combined effect on post-operative macular changes.

Conclusion

The present study sheds light on the impact of cataract surgery on macular morphology and visual function in diabetic patients, providing valuable insights into potential changes and associations with various diabetic characteristics. The significant increase in foveal thickness following surgery, coupled with improvements in best-corrected visual acuity (BCVA), underscores the positive association between macular changes and enhanced vision function postoperatively. Furthermore, our observations suggest potential associations between specific diabetic characteristics and the magnitude of post-operative foveal thickening. Insulin dependence, longer diabetes duration (>10 years), and worse pre-operative diabetic retinopathy severity were linked to a greater increase in foveal thickness, highlighting the importance of considering individual patient factors in surgical decision-making and postoperative management.

Comparison with existing research reveals consistency with previous findings regarding demographics and improvements in BCVA post-surgery. However, further exploration of socioeconomic disparities in access to surgery and the association between diabetic characteristics and post-operative changes is warranted.

Despite the study's limitations, including a moderate sample size and limited follow-up period, our findings have important clinical implications. They suggest that cataract surgery can lead to improvements in both visual function and macular morphology in diabetic patients. However, the observed associations with diabetic characteristics emphasize the need for personalized treatment plans to optimize patient care.

Looking ahead, larger, more diverse studies with longer follow-up periods are needed to confirm our findings and elucidate the underlying mechanisms of post-operative macular changes. Exploring potential interactions between diabetic characteristics and their combined effect on surgical outcomes will be crucial for guiding tailored surgical approaches and improving long-term patient outcomes.

In conclusion, our study contributes to the growing body of knowledge on the effects of cataract surgery in diabetic patients. By understanding the potential influence of diabetic characteristics, we can move towards more personalized surgical approaches and improved patient care, ultimately enhancing visual outcomes and quality of life for diabetic individuals undergoing cataract surgery.

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