

## A Prospective Study to Evaluate Changes in Macular Thickness after Uncomplicated Cataract Surgery Using OCT In Diabetic Patients

Shashwat Singh<sup>1</sup>, Farhat Abrar<sup>2\*</sup>, V.K Malik<sup>3</sup>

<sup>1</sup>JR-3, Department of Ophthalmology, Subharti Medical College, SVSU, Meerut, Uttar Pradesh, India

<sup>2</sup>Associate Professor, Department of Ophthalmology, Subharti Medical College, SVSU, Meerut, Uttar Pradesh, India

<sup>3</sup>Professor and Head of Department, Department of Ophthalmology, Subharti Medical College, SVSU, Meerut, Uttar Pradesh, India

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### Abstract

**Objectives:** To evaluate changes in macular thickness after uncomplicated cataract surgery using OCT in diabetic patients. **Material and Method:** The present prospective observational study was conducted in the department of Ophthalmology at Chhatrapati Shivaji Subharti Hospital from December 2019 to June 2020. All patients with Cataract of either gender above 18 years of age were included in the study and were further divided into two groups i.e. group A (Study group) having diabetic patients with cataract and group B (Control group) containing non-diabetic patients with cataract. The surgery involved 2.2 mm corneal incision, capsulorhexis, hydrodissection, and ultimately intraocular lens implantation. On each follow-up visit at 1st week, 3rd week and 2nd month both the groups were evaluated for macular thickness using OCT at 1st week, 3rd week and 2nd month. Any progression or worsening of macular edema in diabetic patients post-operatively was assessed. Also, the correlation of grade of DR with macular thickness was done. **Results:** Pre-operatively there was no significant difference among group A and B w.r.t. mean foveal thickness as  $p > 0.05$ . Post-operatively (2 month) mean foveal thickness increased more in group A (study group) as compared to group B (control group) with statistically significant difference. As the staging of DR become severe, MFT also increases with statistically significant difference. **Conclusion:** Increase in central macular thickness occurs after uncomplicated phacoemulsification either in diabetic or in nondiabetic patients; the range of increased central macular thickness is more in diabetic patients, especially in patients who already have higher central macular thickness or higher grade of DR initially.

**Keywords:** Diabetes, Macular Thickness, Diabetic retinopathy

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### Introduction

Cataract is the leading cause of blindness in the world and the most prevalent ocular disease. Cataract accounts for 47.8% of the world's roughly 37 million blind individuals. Of note, approximately 90% of the contribution of cataract to blindness was seen in developing countries[1]. The visual outcome of cataract surgery depends upon various factors like condition of the cornea, type of cataract, manipulation of iris, presence of pre-existing ocular conditions like chronic uveitis, any associated systemic disease, and occurrence of intra-operative complications and also experience of the surgeon[2]. Diabetes mellitus increases the probability of developing cataract and the risk of decreased visual outcomes after cataract surgery[3,4]. Diabetic patients pose a particular challenge because of the tendency for early formation of cataract in them and propensity to develop macular edema after cataract surgery[5,6].

The principles and type of cataract surgery have evolved over the past few decades. Manual small-incision cataract surgery (MSICS) is a cost-saving procedure and is suitable for developing countries. MSICS is significantly faster, less expensive, and less dependent on technology than phacoemulsification[7,8]. Although 16 to 30% of patients who have undergone uncomplicated extracapsular cataract surgery will show signs of cystoid macular edema (CME) on fluorescein angiography, few will experience a significant effect on their vision, and less than 2.5% will suffer a permanent visual deficit as a result[9,10]. Still, CME is the most common cause of unexpected poor vision following cataract surgery.

The macular thickness can be measured using optical coherence tomography (OCT), and some studies have reported increased aqueous flare values in patients with CME after cataract surgery. CME in OCT appears as a collection of hypo-reflective spaces within the retina, with an overall increase in macular thickening and loss of the foveal depression. OCT is as effective as FFA at detecting macular edema, while it produces highly reproducible measurements so that serial examination may be used for follow up[11].

There are some controversies in the results of the studies reporting developed increase in central macular thickness (CMT) or macular edema after cataract surgery in patients with diabetes but no diabetic retinopathy (in diabetic patients without diabetic retinopathy). The risk for development of macular edema in diabetics without retinopathy (RR 1.80) was reported to be higher than in the population without diabetes (RR 1.17)[12]. On the contrary, a recently published meta-analysis showed no statistically significant increase in CMT values after cataract surgery in diabetic patients

\*Correspondence

Dr. Farhat Abrar

Associate Professor, Department of Ophthalmology, Subharti Medical College, SVSU, Meerut, Uttar Pradesh, India

E-mail: [dr.farhat.abrar@gmail.com](mailto:dr.farhat.abrar@gmail.com)

without diabetic retinopathy at 1, 3 and 6 months after cataract extraction[13]. On the other hand, Katsimpris et al. found increased macular thickness after uncomplicated cataract surgery in diabetics without retinopathy compared to preoperative values or to a control group of patients at all follow-ups up to twelve months after cataract surgery[14].

As, there are conflicting reports in literature on the effect of cataract surgery on macular thickness in diabetic patient, so this study was planned to see the frequency of development of ME in diabetic patients as compared to non-diabetics and also to see the progression of ME after cataract surgery.

#### Material and Method

The present prospective observational study was conducted in the department of Ophthalmology at Chatrapati Shivaji Subharti Hospital from December 2019 to June 2020. Patients were enrolled in the study after obtaining written informed consent and approval from Institutional Ethical Committee. All patients with Cataract of either gender above 18 years of age were included in the study. As this is a time bound study, we recruited minimum of 100 eyes in each group. Patients were further divided into two groups:

#### GROUP A (Study group)

- (a) Known case of Type 2 Diabetes Mellitus (DM)
- (b) Patients having fasting plasma glucose (FPG) of more than or equal to 126 mg/dl or a 2-hour post prandial plasma glucose (PPBG) of more than or equal to 200mg/dl.

#### GROUP B (Control group)

- (a) Patients with no past history of type 2 DM.
- (b) Patients with FPG less than 126mg/dl or PPBG of less than 200mg/dl.

#### Exclusion criteria

1. Patients with any complication during cataract surgery.
2. Patients with any ocular or systemic condition that can cause macular edema.
3. Patients with any ocular trauma.
4. Patients with history of vitreo-retinal surgery or glaucoma surgery in the same eye.
5. Patients with presence of any retinal or choroidal disease other than diabetes in the same eye.
6. Patients with history of treatment for Diabetic Macular edema or proliferative diabetic retinopathy within 6 months prior surgery.
7. Patients with any other ocular / systemic co-morbidities which will hinder fundus examination and OCT.
8. Patients not signing the informed consent.

#### Procedure

1. Patients presenting in OPD with complaint of Diminution of vision, were asked a detailed ocular and systemic history.
2. Patients underwent an initial work-up such as: BCVA, Slit lamp examination, IOP measurement and Un-dilated fundus examination.

3. Patients selected for cataract surgery were sub-divided into GROUP A (Study group) having diabetic patients with cataract and GROUP B (Control group) containing non-diabetic patients with cataract.
4. Patients of both the group underwent routine pre-operative investigations such as OCT and dilated fundus examination (where possible).
5. All Patients were evaluated for Post prandial blood glucose levels and HBA1C levels (where required).
6. All the patients were evaluated for the macular thickness using OCT.
7. Cataract surgeries were performed by the experienced surgeon.

#### Surgery

One hour before surgery, pharmacologic mydriasis was induced in all patients by the instillation of phenylephrine 2.5% and tropicamide 1% eyedrops. Topical anesthesia was performed by administering eye drops of paracain. The surgery involved 2.2 mm corneal incision, capsulorhexis, hydrodissection, and ultimately intraocular lens implantation. The postoperative therapy prescribed for these patients provided eye drops of tobramycin and dexamethasone in decreasing doses for 4 weeks. On each follow-up visit at 1st week, 3rd week and 2nd month both the groups underwent post-operative investigations such as BCVA, Slit lamp examination, IOP measurement, Dilated fundus examination. All the patients were evaluated for macular thickness using OCT at 1st week, 3rd week and 2nd month.

#### Evaluation of Macular thickness

It was done using OPTOVUE RTvue 100 OCT. After pupil dilation, the patient was seated at the machine, asked to fixate at the internal fixation point and scan is obtained. The macular thickness map was taken to measure the thickness of macula. CSME was diagnosed based on the modified ETDRS protocol." Retinal thickening at or within 500 um of centre of macula; hard exudates at or within 500 um of centre of the macula if associated with adjacent retinal thickening ; zone or zones of retinal thickening 1 disc area in size, at least part of which was within 1 disc diameter of centre of macula.

#### Evaluation

After the initial approach and group assignment, the objective assessment of macular thickness in diabetic patients pre-operatively and post operatively was compared. Any progression or worsening of macular edema in diabetic patients post-operatively was assessed. Also, the correlation of grade of DR with macular thickness was done.

#### Statistical analysis

Data was analysed using SPSS software version 24. Anova, t and chi square tests were used to find the statistical significant difference between the groups.

#### Results

Females were slightly more as compared to males in our study among both the groups. Mean age among group A and B was 54.89±6.53 and 56.41±5.94 years respectively with statistically insignificant difference as  $p > 0.05$  (table 1).

**Table 1: Gender and age distribution among the study groups**

Gender	Group A (Study group)		Group B (Control group)		Chi Square	p value
	N	%	N	%		
Male	48	48	44	44	0.39	0.56
Female	52	52	56	56		
Total	100	100	89	100		
<b>Age</b>					<b>t test</b>	<b>p value</b>
Mean	54.89		56.41		1.17	0.42
SD	6.53		5.94			

Before the surgery, mean foveal thickness (optical coherence tomography) among the diabetic subjects was 251.67±31.32 which increased to 307.13±58.19 post cataract surgery. Before and after the cataract surgery, mean foveal thickness (optical coherence tomography) among the non-diabetic subjects was 231.76±20.37 which increased to 267.58±21.41 post cataract surgery. Pre-operatively there was no significant difference

among group A and B w.r.t. mean foveal thickness as  $p>0.05$ . Post-operatively (2 month) mean foveal thickness increased more in group A (study group) as compared to group B (control group) with statistically significant difference (table 2).

**Table 2: Comparison between mean foveal thickness (pre-postoperative optical coherence tomography) among the group A and B**

Mean Foveal Thickness	Group A (Study group)		Group B (Control group)		Unpaired t test	p value
	Mean	SD	Mean	SD		
Pre	251.67	31.32	231.76	20.37	2.61	0.10
3 <sup>rd</sup> Week	268.92	37.74	240.35	24.18	4.38	0.024*
2 <sup>nd</sup> Month	307.13	58.19	267.58	21.41	4.89	0.009*
Anova test	8.92		6.98			
p value	<0.01*		<0.01*			

\*: statistically significant

Table 3 shows the comparison of mean logarithm of minimal angle of resolution visual acuity (pre-postoperative optical coherence tomography) among the study groups. Pre-operatively there was no significant difference among group A and B w.r.t. mean logarithm of minimal angle of resolution visual acuity as  $p>0.05$ . Post-operatively mean logarithm of minimal angle of resolution visual acuity decreased more in group B (control group) as compared to group A (study group) with statistically significant difference.

**Table 3: Comparison between mean logarithm of minimal angle of resolution visual acuity (pre-postoperative optical coherence tomography) among the study groups**

Mean Foveal Thickness	Group A (Study group)		Group B (Control group)		t test	p value
	Mean	SD	Mean	SD		
Pre	0.83	0.09	0.81	0.06	0.21	0.68
Post	0.40	0.22	0.27	0.09	5.62	0.007*

\*: statistically significant

As the staging of DR become severe, MFT also increases with statistically significant difference. Mean MFT thickness was  $302.04\pm 26.51$ ,  $334.73\pm 34.68$  and  $426.11\pm 72.31$  among subjects having mild, moderate and severe DR respectively (table 4).

**Table 4: Staging of diabetic retinopathy and mean foveal thickness postoperatively in the diabetic group**

Staging of DR	MFT (Postoperative OCT)		Anova Test	p value
	Mean	SD		
None	265.79	35.86	11.46	<0.01*
Mild	302.04	26.51		
Moderate	334.73	34.68		
Severe	426.11	72.31		

\*: statistically significant

## Discussion

Clinically significant macular oedema (CSME) is an important risk factor for decreased vision after cataract surgery. Thus, after cataract surgery, angiographic ME in diabetic patients may be from pseudophakic CME or from diabetic macular edema (DME), and by itself may not be clinically useful in predicting visual acuity (VA); however, macular thickening may be clinically important. Moreover, Kim et al published reports that the level of DR is a risk factor for thickening of the retina after cataract surgery[15]. Hence this prospective study was planned to evaluate changes in macular thickness after uncomplicated cataract surgery using OCT in diabetic patients. Females were slightly more as compared to males in our study among both the groups. El-Saadani et al[5] in their study revealed similar findings too. Açar et al[16] too revealed no statistical difference between the gender distributions of the diabetic and nondiabetic groups. Hammam MHA et al[17] too revealed slightly more females as compared to males in their study.

Mean age among group A and B was  $54.89\pm 6.53$  and  $56.41\pm 5.94$  years respectively with statistically insignificant difference as  $p>0.05$  in our study. Açar et al[16], Hammam MHA et al[17] and El-Saadani et al[5] revealed similar results too.

In the present study, pre-operatively there was no significant difference among group A and B w.r.t. mean foveal thickness as  $p>0.05$ . Post-operatively mean foveal thickness increased more in group A (study group) as compared to group B (control group) with statistically significant difference. Oh et al[18] showed that diabetic patients may be susceptible to developing postoperative subclinical retinal swelling or clinical ME after cataract surgery. Similarly El-Saadani et al[5] reported that in the diabetic group, the MFT increased significantly from  $254.88 \pm 32.53$  initially to  $310.52 \pm 64.74$  at 1 month postoperatively ( $P = 0.001$ ). In the control group, the MFT increased significantly from  $228.28 \pm 18.65$  initially to  $269.16 \pm 23.59$

at 1 month postoperatively. Post-operatively mean foveal thickness increased more in diabetic group as compared to non-diabetic group with statistically significant difference. Dowler et al[19] showed that DME progressed in ~20–40% of eyes that underwent cataract surgery, but in a considerable percentage of these eyes the ME resolved spontaneously. Accordingly, these studies suggested that progression of DME may be classified as follows: a transient pseudophakic ME (Irvine-Gass syndrome) or a substantial progression of diabetic maculopathy. Moreover, the study has demonstrated that MFT in nondiabetic patients after uncomplicated phacoemulsification increases significantly at 1 month postoperatively, and MFT increases more significantly in diabetic patients than in the control group at 1 month postoperatively. Biro and Balla[11] compared the CMT of 18 eyes of diabetic patients with 36 eyes of nondiabetic patients using SD-OCT preoperatively and at 1, 7, 30, and 60 days post-op, with the contralateral eye acting as the control. Patients with any other ophthalmic pathologies were excluded, as well as those with severe NPDR or with proliferative DR. A significant increase was noted in the CMT in both the groups with DM and without DM as compared with their respective controls.

In this study, before the surgery, mean logarithm of minimal angle of resolution visual acuity (optical coherence tomography) among the diabetic subjects was  $0.83\pm 0.09$  which decreased to  $0.40\pm 0.22$  post cataract surgery with statistically significant difference. Before the surgery, mean logarithm of minimal angle of resolution visual acuity (optical coherence tomography) among the non-diabetic subjects was  $0.81\pm 0.06$  which decreased to  $0.27\pm 0.09$  post cataract surgery with statistically significant difference. Pre-operatively there was no significant difference among group A and B w.r.t. mean logarithm of minimal angle of resolution visual acuity as  $p>0.05$ . Post-operatively mean logarithm of minimal angle of resolution visual acuity decreased more in group B (control group) as compared to group A

(study group) with statistically significant difference. Eriksson et al[20] showed that the visual outcome in diabetic eyes with mild to moderate retinopathy is as good as in the control group 6 months after cataract surgery. However, at 6 weeks there was a significant difference, with lower VA in eyes with DR combined with a higher frequency of macular changes both on fluorescein angiography and on OCT, when compared with the control group. Kim et al[15] found a good correlation between BCVA and retinal thickening. However, other reports show only a moderate correlation between central retinal thickness and VA in patients with DME, implying that VA may depend mainly on the disruption of the retinal architecture or on direct photoreceptor damage. In our study, as the staging of DR become severe, MFT also increases with statistically significant difference. Mean MFT thickness was  $302.04 \pm 26.51$ ,  $334.73 \pm 34.68$  and  $426.11 \pm 72.31$  among subjects having mild, moderate and severe DR respectively. El-Sobkya et al[21] showed that uncomplicated phacoemulsification does not cause acceleration of DR postoperatively. Moreover, ME, which is common after cataract surgery, may follow a benign course and any progression that is observed postoperatively probably represents natural progression rather than being a direct effect of surgery. Kim et al[15] suggested that there was an association between the level of DR and central retinal thickening. The increase in the central retinal thickness in subjects with moderate or severe NPDR or PDR was much higher than in the patients without DR[2]. Similarly El-Saadani et al[5] found that there was a statistically significant correlation between postoperative MFT and staging of DR in the diabetic group. There are certain limitations of this study. There were a relatively small number of cases included, and the optical coherence tomography measurements were not repeated. Thus this study has demonstrated that MFT, after uncomplicated phacoemulsification, in diabetic patients increases significantly at 1 month postoperatively, and there is a greater increase in MFT in diabetic patients with a higher grade of DR and with higher initial MFT.

#### Conclusion

Diabetic patients pose a particular challenge due to their early formation of cataracts and propensity to develop macular edema and progression of retinopathy after cataract surgery. Increase in central macular thickness occurs after uncomplicated phacoemulsification either in diabetic or in nondiabetic patients; the range of increased central macular thickness is more in diabetic patients, especially in patients who already have higher central macular thickness or higher grade of DR initially. Despite increased MFT, BCVA improved postoperatively in both groups. It is therefore important to distinguish which specific factors in individual patients who develop CME are vital, so that targeted therapies may be developed.

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