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Original Research Article

TO STUDY THE CENTRAL MACULAR THICKNESS CHANGES FOLLOWING UNCOMPLICATED PHACOEMULSIFICATION IN DIABETIC PATIENTS WITHOUT RETINOPATHY

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Abstract

Background: To investigate the changes in macular thickness following uncomplicated phacoemulsification in diabetic patients without retinopathy and non-diabetic individuals, both preoperatively and postoperatively after 6 weeks; and assess the correlation between macular thickness changes and best-corrected visual acuity after phacoemulsification cataract surgery. **Materials and Methods:** It was hospital based prospective, observational study, the study conducted in the department of Ophthalmology M.G.M Medical College and L.S.K. Hospital Kishanganj, Bihar. Total 50 patients were enrolled for the study. (25 eyes in Case group and 25 eyes in control group). Patients underwent Phacoemulsification using a 2.8 mm superior or supero temporal clear corneal incision with a stop and chop and direct chop technique. Follow up of the patients was done at 6 weeks after the surgery, The period of the study was December 2020 to November 2022. **Result:** The mean age was calculated and was 58.60 ±8.52 years for the case group and 59.12 ±8.98 years for the control group. The results showed that 11 Patients (44.0%) in the case group were male and 14 Patients (56.0%) were female. In the control group, there were 13 Patients (52.0%) who were male and 12 Patients (48.0%) who were female. A chi-square value of 0.321 and a p-value of 0.571. The results show that there was no statistically significant difference in BCVA between the case and control groups before & after 6 weeks of surgery the p value was (p=0.204)& (p=0.317). However, there was a significant difference in BCVA between the inter groups 6 weeks after surgery (p<0.0001). The CMT was measured before the operation (Pre-operative) and 6 weeks after the operation (Postoperative Week 6). The results show that there was a significant increase in CMT in both groups after the operation (p<0.0001). The mean CMT was 262.36 ± 21.75 µm in the Case Group and 255.04 ± 21.82 µm in the Control Group before the operation, with no significant difference between the two groups (p=0.799). The results show that there was a significant increase in CMT in both groups after the operation (p-value is <0.05, meaning significant). The mean CMT was 264.08 ± 21.84 µm in the Case Group and 256.20 ± 20.93 µm in the Control Group before the operation, with no significant difference between the two groups (p=0.938).**Conclusion:** Present study highlights a higher incidence of increase of central macular thickness following routine cataract phacoemulsification surgery in diabetic patients that had no evidence of diabetic retinopathy preoperatively. OCT was a useful, non-invasive diagnostic tool in determining CMT post cataract surgery; however the increase is more in well controlled diabetic patients than non-diabetic patients. The short-term post phacoemulsification surgery visual recovery in diabetic patients without retinopathy may not be different from the non-diabetic group. The etiology, pathogenesis, prevention and potential treatment of this complication warrants further clinical studies of larger scale in order to be evaluated in detail.

INTRODUCTION

Cataract is the leading cause of blindness globally. Though the problem of cataract blindness is prevalent all over the world, it is more severe in the developing nations because of the backlog of untreated cataracts and underutilization of existing resources.[1] According to a national survey, in India 62.6% of the blindness in the population above 50 years of age is cataract related.[2]

An estimated 3.8 million persons become blind from cataract each year in India and 2.5 to 5.8 million sight restoring operations are needed to be performed every year to control cataract related blindness in India.[3]

In the recent years we have seen great progress in cataract surgery, both in the surgical technique as well as with modern phacoemulsifiers. In addition to the design and construction of intraocular lenses which have allowed faster and cleaner surgery with much lower complication rates in comparison to intracapsular and even extracapsular techniques.

Irvine,[4] in 1953 first described the presence of macular edema following cataract surgery. Later, in 1966, Gass and Norton further analyzed this edema with biomicroscopic and angiographic evaluation. This complication is referred to as cystoid macular edema (CME) or pseudophakicedema or the "Irvine-Gass syndrome".[5] It is more frequently observed after a complicated cataract case, although it may also occur following routine cataract surgery.[6] CME after cataract surgery delays visual recovery, but is usually transient and the prognosis is generally good Nevertheless, some patients may experience chronic cystic alterations in the macula, with subsequent Cystoid macular edema (CME) following uneventful cataract surgery is recognized as the most common cause of decreased vision postoperatively.

CME documented by biomicroscopy is termed clinical CME.[5,6] On the contrary, when it is revealed by means of fluorescein angiography, it is referred as subclinical CME.[5,6] Subclinical CME (or angiographic edema) can often be recorded without visual impairment.

Although angiography with fluorescein is usually utilized to confirm the diagnosis of CME. This procedure can cause severe complications and there is not always a correlation between the degree of hyperflourescence and visual loss.

The introduction of O.C.T. which is a non-invasive comfortable method has enabled clinicians to reliably detect and measure small changes in macular thickness in case of clinical and sub-clinical pseudophakic CME and to quantitatively evaluate the efficacy of different therapeutic modalities. The changes in the parameters may allow us to assess progression of disease and success of therapy and helpful in patients not achieving log MAR unit 0.[7] This may be important for establishing treatments to avoid the visual loss postoperatively.[8]

Diabetes mellitus is one of the most common microangiopathies that has a multi-organ effect and can lead to serious complications. One of the most common microvascular representations of chronic DM is diabetic retinopathy (DR).[9] For decades the diagnostic criteria was based on either fasting plasma glucose or 2 hours postprandial glucose. Uncontrolled HbA1c levels are correlated with development of DR in the form of retinal haemorrhages, ischemia, neovascularisation and macular edema.[10]

Visual prognosis following cataract surgery in patients with diabetes depends on the severity of existing diabetic retinopathy (DR) and possible aggravation after cataract surgery. Increase in the levels of vascular endothelial growth factor (VEGF) and other inflammatory cytokines occur after surgical trauma and subsequent inflammation following cataract surgery in diabetic eyes.[11]

These factors compromise the retinal vasculature as well as its ability for recovery following surgery, and they eventually lead to macular edema.

Macular oedema is known to occur in a wide variety of ocular conditions including uveitis, trauma, vascular retinopathies, vitreoretinal adhesions, intraocular surgery, macular degeneration. hereditary dystrophies, diabetes, and age-related [12]

MATERIALS AND METHODS

It was hospital based prospective, observational study, the study conducted in the department of Ophthalmology M.G.M Medical College and L.S.K. Hospital Kishanganj, Bihar. Total 50 patients were enrolled for the study. (25 eyes in Case group and 25 eyes in control group). Patients underwent Phacoemulsification using a 2.8 mm superior or supero temporal clear corneal incision with a stop and chop and direct chop technique. Follow up of the patients was done at 6 weeks after the surgery, The period of the study was December 2020 to November 2022.

Inclusion Criteria

- Well controlled DM type 2
- Age >40 years and above
- Patients with senile cataract
- Well dilating pupil
- Normal individuals without diabetic retinopathy

Exclusion Criteria

- Patients with preexisting macular pathologies such as macular hole or age related macular degeneration
- Other retinopathies such as retinal vascular occlusion or retinal dystrophy
- Pre-existing ocular diseases such as glaucoma or uveitis
- Patients with any intra-operative complications such as posterior capsule rupture, vitreous loss and iris prolapse
- Previous intraocular surgery or laser treatment except for cataract surgery in the fellow eye

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- Use of any systemic medication with known interference on retinal thickness.

Examination of Patient

A complete ocular examination was done for all patients. Examination was done pre-operatively and postoperatively.

Pre operative examination consisted of the following:

- Determination of best corrected visual acuity(BCVA) by Snellen's chart;
- Slit lamp examination of the anterior segment;
- Slit lamp biomicroscopy of the fundus using + 90D lens;
- OCT macular scan using Topcon 3D- OCT Maestro2, line scans through the fovea, retinal thickness analysis
- Patency of the naso-lacrimal duct by syringing;
- Axial length using A Scan, and;
- General examination

Post - operative examination included the following:

- Determination of the best corrected visual acuity
- Slit lamp examination of the anterior segment
- Slit lamp biomicroscopy of the fundus using +90D lens;
- OCT macular scan.

Surgical Technique

Patients underwent Phacoemulsification using a 2.8 mm superior or supero temporal clear corneal incision with a stop and chop and direct chop technique.

Follow up of the patients was done at 6 weeks after the surgery.

Interpretation of the OCT scans

patients were evaluated pre operatively and post operative week 6 for

Changes of macular thickness using OCT (Topcon 3D OCT Maestero 2)

Central subfield retinal thickness which is the thickness of the retina in a disc shaped region of 1mm diameter centered on fovea.

Inner subfield retinal thickness is the average thickness of the retina in each inner quadrant of an annulus centered on the fovea with inner 1mm diameter and outer 3mm diameter.

Outer subfield retinal thickness is the average thickness of the retina in each outer quadrant of an annulus centered on the fovea with inner 3mm diameter and outer 6mm diameter. Data analysis was performed using the mean of the values of the four quadrants.

RESULTS

The age group distribution of 25 individuals in the case group and 25 individuals in the control group was analyzed. The results show that in the 40-50 years age group, there were 2 patients (8.0%) in the case group and 1 patient (4.0%) in the control group. In the 51-60 years age group, there were 15 patients (60.0%) in the case group and 18 patients (72.0%) in the control group. In the 61-70 years age group, there were 5 patients (20.0%) in the case group and 2 patients (8.0%) in the control group. In the 71-80 years age group, there were 2 patients (8.0%) in the case group and 3 patients (12.0%) in the control group. And in the group of individuals over 80 years old, there was 1 patient (4.0%) in both the case group and the control group. The mean age was calculated and was 58.60 ±8.52 years for the case group and 59.12 ±8.98 years for the control group. A statistical inference was performed and the result was 0.736, which suggests that there is no significant difference in the mean age between the two group. [Table 1]

The distribution of male and female participants in a case group (25) and a control group (25) was analyzed. The results showed that 11 Patients (44.0%) in the case group were male and 14 Patients (56.0%) were female. In the control group, there were 13 Patients (52.0%) who were male and 12 Patients (48.0%) who were female. A chi-square value of 0.321 and a p-value of 0.571, which suggests that there is no significant difference in the distribution of male and female participants between the case group and the control group. [Table 2]

The laterality distribution of 25 individuals in the case group and 25 individuals in the control group was analyzed based on their affected eye. The results showed that 14 Patients (56.0%) in the case group had the right eye affected, and 11 Patients (44.0%) had the left eye affected. In the control group, 15 Patients (60.0%) had the right eye affected, and 10 Patients (40.0%) had the left eye affected. A chi-square test was performed and the result showed a chi-square value of 0.082 and a p-value of 0.774, which suggests that there is no significant difference in the laterality distribution of the affected eye between the case group and the control group. [Table 3]

The LOCS grading system was used to categorize 25 individuals in the case and 25 individuals in the control group based on the severity of their cataract. The results showed that the distribution of the severity of cataracts between the two groups was not significantly different. The result showed a chi-square value of 3.511 and a p-value of 0.940, which suggests that there is no significant difference in the distribution of the severity of cataracts between the case group and the control group. [Table 4]

The results show that there was no statistically significant difference in BCVA between the case and control groups before & after 6 weeks of surgerythe p value was (p=0.204)& (p=0.317). However, there was a significant difference in BCVA between the inter groups 6 weeks after surgery (p<0.0001). Both groups had a significant improvement in BCVA after surgery compared to their pre-operative values. [Table 5]

The Central Macular Thickness (CMT) at a 1mm radius was measured in two groups of 25 individuals each, the "Case Group" and the "Control Group".

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The CMT was measured before the operation (Pre-operative) and 6 weeks after the operation (Postoperative Week 6). The results show that there was a significant increase in CMT in both groups after the operation ($p<0.0001$). The mean CMT was 262.36 ± 21.75 μm in the Case Group and 255.04 ± 21.82 μm in the Control Group before the operation, with no significant difference between the two groups ($p=0.799$). Six weeks after the operation, the mean CMT was 271.84 ± 20.42 μm in the Case Group and 260.20 ± 20.33 μm in the Control Group, with a significant difference between the two groups ($p=0.023$). [Table 6]

The Central Macular Thickness (CMT) at a 3mm radius was measured in two groups of 25 individuals each, the "Case Group" and the "Control Group". The CMT was measured before the operation (Pre-operative) and 6 weeks after the operation (Postoperative Week 6). The results show that there was a significant increase in CMT in both groups after the operation (p-value is "sig", meaning significant). The mean CMT was 256.32 ± 21.69 μmin the Case Group and 261.40 ± 21.34 μm in the Control Group before the operation, with no significant difference between the two groups ($p=0.833$). Six weeks after the operation, the mean CMT was 272.56 ± 21.85 μm in the Case Group and 263.60 ± 21.64 μm in the Control Group, with a significant difference between the two groups ($p=0.012$). [Table 7]

The Central Macular Thickness (CMT) at a 6mm radius was measured in two groups of 25 individuals each, the "Case Group" and the "Control Group". The CMT was measured before the operation (Pre-operative) and 6 weeks after the operation (Postoperative Week 6). The results show that there was a significant increase in CMT in both groups after the operation (p-value is <0.05, meaning significant). The mean CMT was 264.08 ± 21.84 μm in the Case Group and 256.20 ± 20.93 μm in the Control Group before the operation, with no significant difference between the two groups ($p=0.938$). Six weeks after the operation, the mean CMT was 271.36 ± 21.77 μm in the Case Group and 256.28 ± 20.70 μm in the Control Group, with a significant difference between the two groups ($p=0.003$). [Table 8]

Table 1: Age Distribution

Age Group	Case Group (n=25)		Control Group (n=25)	
	Frequency	Percentage	Frequency	Percentage
40-50 years	2	8.0	1	4.0
51-60 years	15	60.0	18	72.0
61-70 years	5	20.0	2	8.0
71-80 years	2	8.0	3	12.0
>80 years	1	4.0	1	4.0
Total	25	100.0	25	100.0
Mean Age	58.60 ±8.52		59.12 ±8.98	
Statistical Inference	0.736			

Table 2: Sex Distribution

Sex	Case Group (n=25)		Control Group (n=25)	
	Frequency	Percentage	Frequency	Percentage
Male	11	44.0	13	52.0
Female	14	56.0	12	48.0
Total	25	100.0	25	100.0
Statistical Inference	Chi square: 0.321p value: 0.571			

Table 3: Laterality

Laterality	Case Group (n=25)		Control Group (n=25)	
	Frequency	Percentage	Frequency	Percentage
Right Eye	14	56.0	15	60.0
Left Eye	11	11.0	10	40.0
Total	25	100.0	25	100.0
Statistical Inference	Chi square: 0.082p value: 0.774			

Table 4: Distribution according to LOCS grading

LOCS grading	Case Group (n=25)		Control Group (n=25)	
	Frequency	Percentage	Frequency	Percentage
CNS1	2	8.0	3	12.0
CNS1P	2	8.0	1	4.0
CNS2	8	32.0	9	36.0
CNS2P	1	4.0	2	8.0
CNS3	1	4.0	2	8.0
CP	1	4.0	1	4.0
NS1P	3	12.0	2	8.0
NS2	6	24.0	3	12.0
NS2P	0	0.0	1	4.0
NS3	1	4.0	1	4.0

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Total	25	100.0	25	100.0
Statistical Inference	Chi square:3.4588p value:0.943			

Table 5: Comparison of BCVA between Case and Control Group and of the difference over the periods of 6 weeks Follow Up

BCVA	Case Group (n=25)		Control Group (n=25)		p value
	Mean	±SD	Mean	±SD	
Pre-operative	0.98	±0.12	0.97	±0.14	0.204
Postoperative Week 6	0.26	±0.20	0.22	±0.16	0.317
p value	<0.0001		<0.0001		

Table 6: Comparison of Central Macular Thickness at 1 mm radius between Case and Control Group and of the difference over the periods of 6 weeks Follow Up

CMT (1mm radius)	Case Group (n=25)		Control Group (n=25)		p value
	Mean	±SD	Mean	±SD	
Pre-operative	262.36	±21.75	255.04	±21.82	0.799
Postoperative Week 6	271.84	±20.42	260.20	±20.33	0.023
p value	<0.0001		<0.0001		

Table 7: Comparison of Central Macular Thickness at 3 mm radius between Case and Control Group and of the difference over the periods of 6 weeks Follow Up

CMT (3 mm radius)	Case Group (n=25)		Control Group (n=25)		p value
	Mean	±SD	Mean	±SD	
Pre-operative	256.32	±21.69	261.40	±21.34	0.833
Postoperative Week 6	272.56	±21.85	263.60	±21.64	0.012
p value	<0.0001		<0.001		

Table 8: Comparison of Central Macular Thickness at 6 mm radius between Case and Control Group and of the difference over the periods of 6 weeks Follow Up

CMT (6 mm radius)	Case Group (n=25)		Control Group (n=25)		p value
	Mean	±SD	Mean	±SD	
Pre-operative	264.08	±21.84	256.20	±20.93	0.938
Postoperative Week 6	271.36	±21.77	256.28	±20.70	0.003
p value	<0.0001		0.028		

DISCUSSION

In the present study we evaluated changes in central retinal thickness in diabetic patients without retinopathy and in non-diabetic controls. The result revealed that an increase in central retinal thickness was found with 6 weeks postoperatively in both groups. (p<0.001).

In both groups the central retinal thickness increased after cataract surgery from preoperative and had significantly increased at 6 weeks postoperatively. However the visual acuity did not deteriorate even though the central retinal thickness increased at postoperative visit (p=0.317).

When we compared the central retinal thickness between the two groups there was statistically significant increase in diabetics as compared to non-diabetics (p=<0.001). None of the patient in any group developed cystoid macularedema.

Demographic profile

Most of the patients in the present study were in 51-60years of age(72% in controls and 60%in cases). Mean age was 59.12+_8.98 andamongcases was 58.60 +_ 8.52 years. This is in accordance with the study conducted by Roy B in 2017 where most of the patients were in similar age group.

Use of OCT for measurement of macular thickness

We used OCT for the measurement of macular thickness prior to and 6 weeks after cataract surgery. In the past, only qualitative and semi qualitative measurements of macular thickening, by either biomicroscopy examinations of FA could be used for the detection of macular morphology, and also precise and linear quantitative measurements of macular thickness. OCT is widely employed prior to cataract surgery in order to assess any coexisting retinal disease that can potentially limit the visual outcome postoperatively.[13]

We consider that the study of the variations of macular thickness with OCT is a good method to detect clinical and subclinical pseudo-phakic CME. This may be important for establishing treatments to avoid as far as possible the loss of visual acuity in these patients. OCT is also very useful tool in the differential diagnosis between diabetic CME, if it appears early. in post-op, and pseudo-phakic CM with a lower prognosis and which appears typically one month after surgery.

However in the study conducted by Carl W.Baker et al,[14] in 2013 fluorescein angiographywas performed and sent to fundus photograph reading centre. Classification of macular edema patterns used fluorescein angiography and not OCT. They conducted a multicenter study on patients with diabetic retinopathy without definite central invoved DME preoperatively and found that the chances of manifesting central involved macular edema and or development or progression of macular edema in the non-central sub retinal fields following cataract

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surgery may be influenced by the presence of preexisting DME and history of DME treatment.

U. Eriksson et al,[6] conducted a study in 2010 in which they compared OCT with the gold standard (FA) on postoperative macular change. In diabetic eyes, the incidence of macular changes on FA was considerably higher than on qualitative OCT evaluation, and the correspondence between the two techniques was poor. In control eyes, on the other hand, the incidence and type of macular changes on FA were consistent with those found on OCT. Their study demonstrates that clinical post-surgical CME can be detected with OCT as efficiently as with FA.

In our study we performed spectral domain OCT for all the patients of both the groups i.e diabetics and non-diabetics. It was very effective in detecting any change in macular thickness. We did not do FFA for any patient in the postoperative period.

Macular thickness change on post operative week 6

Our results showed that macular thickness increased postoperatively in both diabetics and non-diabetics when compared to the preoperative values. Preoperative central macular thickness was 255 and 262 in non-diabetics and diabetics respectively whereas at postoperative week 6 it was 260 and 271. (P=<0.001). However, the increase in diabetics was significantly higher as compared to non diabelics P<0.001.

KatsimprisJM et al,[15] conducted a study in 2011 similar to ours and reported that post operative central retinal thicknessin diabetics at all times of follow up period was significantly increased when compareredto controls however unlilke our study they found that the incidence of cystoid macular edema (CME) was 4.0 % and 28 % for the control group and the diabetic group, respectively, at the end of the follow up period (p <0.05). This discrepancy in results may be due to the difference in the follow up criteria which was assessed at 6 months and 12 months, as compared to our study where the last follow up visit was at 6 weeks

Chen X Y et al,[16] in 2016 reported that in diabetic eyes macular thickness of the central subfield as well as the inner and outer rings increase statistically upto 3 months after surgery. However they included eyes with preoperative DME which is in contrast to our study because the patients with any signs of diabetic retinopathy and DME were excluded fromour study.

B Roy,[17] in 2017 found that in the nondiabetic group, there was a statistically significant increase in CRT at postoperative Week 1, Week 2, and postoperative Week 4(p < 0.0001)which is in accordance with our study. In the diabetic without retinopathy group, the CRT at postoperative week 1, Week 2, and Week 4 increased significantly compared to the baseline value (p<0.0001) as found in our study also. The comparison of pre and post operative CRT between both groups, they failed to find any significant differences in mean CRT between the groups preoperatively (p=0.58) and at postoperative day, Week 1, Week 2 and Week4. Whereas in our study a statistically significant difference was found between both the groups at 6 weeks(p=<0.001)

In a recent study by Dr sumedha Sharma,[18] in 2019 Patients who underwent Phacoemulsification showed average Macular thickness of 193.73 on Day1, 197.66 on Day 7 and 202.27 on Day 45.However they compared the central macular thickness after SICS and Phacoemulsification cataract surgery using OCT Methods. They found that the presence of subclinical increase in the central macular thickness following cataract surgery was more following SICS than phacoemulsification and maximum at post op day 45 whereas in our study no patient underwent SICS surgery. All surgeries were performed by phacoemulsification.

Correlation of macular edema with BCVA

In our study we found no correlation of macular thickness with BCVA P=0.317. This might be due to the reason that the increase in macular thickness though statistically significant was small i.e 5-8 microns in non-diabetics and 15-20 microns among diabetics. Thus not affecting the visual acuity.

Kim et al,[19]reportéd that both postoperative macular edema and visual outcomes were significantly worse in the diabetic retinopathy group than in the non-diabetic retinopathy group after cataract surgery. Similar to our study they found that the mean central foveal thickness of diabetic eyes without retinopathy increased by only a very small amount in the short-term postoperative periods whereas they also reported that the mean central foveal thickness in eyes with mild to moderate nonproliferative diabetic retinopathy increased by a far greater amount at the same time periods (127 mm and 117 mm at 1 month and 3 months, respectively). The more prominent increase in macular thickness was also associated with a lesser improvement in postoperative visual outcomes in diabetic retinopathy eyes.

CME

No patient in our study developed cystoid macular edema. The reason for this was that patients with co morbid conditions that increased the risk of macular edema were excluded from the study. Also all the surgeries were uneventful.

In a study conducted by Samantaanupam et al,[20] in 2014, showed that CME occurred postoperatively in 47% without pre-existing DR. Such a high incidence in their study might be due to the co morbid conditions which have been included in the inclusion criteria. Associated morbid conditions, like hypertension, hyperlipidaemia and diabetic nephropathy, when analysed for a possible association for postoperative development of CME by the help of x2 test, positive association was observed in hypertensive patients undergoing phacoemulsification and subsequently developing CME.

After cataract surgery, there is posterior diffusion of inflammatory factors, especially prostaglandins, which is known to cause instability of the blood-

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retina barrier (BRB). The BRB is responsible in maintaining retinal homeostasis and restricting movement of plasma constituents into the retina and the breakdown of BBR causes increased permeability of the perifoveal capillary network, and results in intraretinal fluid accumulation both in intra and extracellular compartment.

CONCLUSION

Present study highlights a higher incidence of increase of central macular thickness following routine cataract phacoemulsification surgery in diabetic patients that had no evidence of diabetic retinopathy preoperatively. OCT was a useful, non-invasive diagnostic tool in determining CMT post cataract surgery; however the increase is more in well controlled diabetic patients than non-diabetic patients. The short-term post phacoemulsification surgery visual recovery in diabetic patients without retinopathy may not be different from the non-diabetic group. The etiology, pathogenesis, prevention and potential treatment of this complication warrants further clinical studies of larger scale in order to be evaluated in detail.

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