



Research Article

Correlation of Central foveal thickness, best corrected visual acuity and cystoid macular edema in diabetic and non-diabetic patients post cataract surgery using Spectral-domain optical coherence tomography

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ABSTRACT

Purpose: To find out and compare Central foveal thickness (CFT), Best Corrected Visual Acuity (BCVA), and Cystoid Macular Edema (CME) after uneventful cataract surgery among normal and diabetic patients without retinopathy using SD-Optical Coherence Tomography (SDOCT).

Study Design: Prospective cohort study

Methods: Patients were divided into 2 groups- Diabetic patients without retinopathy without macular changes and Non-diabetic patients without retinal involvement. Thirty patients were included in each group with a follow-up period of 3 months in which CFT, BCVA, and CME after cataract surgery were compared from pre-op values in both groups.

Statistical analysis used: Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0.

Results: A statistically insignificant difference was found when BCVA was compared among post-op patients in both groups. CFT showed a significant increase when compared to pre-op values in both groups but by the end of 3 months post-op, there was an insignificant decline in CFT in the diabetic group and a significant decline in the non-diabetic group. The incidence of Cystoid Macular Edema (CME) was found to be higher in diabetic patients in this study.

Conclusions: Diabetic patients are more prone to an increase in CFT after cataract surgery without affecting vision as these changes in CFT were at the subclinical level which did not affect BCVA. So OCT is a non-invasive effective tool for detecting subclinical CME and may be used to prevent its progression to clinical CME.

Keywords: CFT, cataract, diabetic, non-diabetic, OCT

INTRODUCTION:

Cataracts are one of the most common causes of blindness worldwide that require surgical removal.¹ Patients with diabetes are at more risk of developing cataracts than non-diabetic patients.² Phacoemulsification with posterior chamber intra-ocular lens is the main surgical procedure for cataracts these days.³

Cystoid macular edema (CME) after cataract surgery delays visual recovery which is generally transient with a good prognosis.⁴ Patients with diabetes, inflammatory conditions, and complicated cataract surgery are at higher risk of developing CME.⁵ Surgery in diabetic eyes increases the levels of vascular endothelial growth factor (VEGF) and other inflammatory cytokines.⁶ These factors lead to compromised retinal vasculature and delayed recovery after surgery, eventually leading to macular edema. In diabetic patients, CME and diabetic macular edema (DME) can affect vision post-cataract surgery.^{5,7,8,9} Since macular edema is more common after cataract surgery in diabetic patients, the need to study the correlation between diabetic and non-diabetic patients is very important.

CME documented by biomicroscopy is termed clinical CME usually associated with visual impairment and CFT >299µm as determined by OCT and when it is revealed only using diagnostic tools, it is referred to as subclinical CME. Subclinical

CME is diagnosed when there is no edema involving the center of the fovea as determined by slit lamp biomicroscopy and CFT of $\geq 250\mu\text{m}$ and $\leq 299\mu\text{m}$

Subclinical CME can often be recorded without visual impairment. The incidences of subclinical CME and clinical CME are reported to be 9.1 – 25.5%¹⁰⁻¹² and 0.6 – 4%¹²⁻¹⁵ respectively, following uneventful phacoemulsification in healthy individuals.

OCT is a non-invasive tool, mainly for retina and optic nerve lesions, and an instrument for detecting sub-clinical CME.¹¹ Chen XY¹⁶ et al in 2016, conducted a study on diabetic patients who underwent cataract surgery and were evaluated before the surgery and 1 and 3 months after surgery using OCT. A statistically significant increase could be detected in the central subfield as well as the perifoveal and parafoveal sectors. Eyes with pre-operative DME before cataract surgery are at higher risk for developing central-involved ME.

Kim SJ¹⁷ et al³¹ in 2007 analyzed that diabetic eyes have a high incidence of increased CFT on OCT after cataract surgery associated with a loss of vision at 1 month with incomplete visual recovery at 3 months.

Since there is a paucity of literature comparing various parameters in a single study we aimed to evaluate and compare BCVA, CFT, and CME after cataract surgery between normal and diabetic patients with type 2 both on insulin and on oral antidiabetic drugs without retinopathy among sex and age-matched in patients, using spectral domain optical coherence tomography (Cirrus HD-OCT, Carl Zeiss Meditec, Dublin, CA, USA).

Subjects and Methods:

It was a Prospective cohort study conducted on 60 eyes (30 diabetic and 30 non-diabetic) who fulfilled all the inclusion criteria over 1 year at Mohan Eye Institute, 11 B Gangaram Marg, New Delhi. The Institutional Ethical Committee approved the study and followed the Helsinki Declaration. Written informed consent was obtained from all patients or their guardians before they participated in the study.

2.1 Inclusion criteria: All subjects who had immature senile cataracts and underwent cataract surgery where OCT could be done and fundus could be examined.

2.2 Exclusion criteria: Patients with eyes having coexisting diabetic retinopathy and macular changes, with any other retinal pathology, patients with mature cataracts, and where media was hazy due to any other pathology were excluded.

2.3 Primary outcome central foveal thickness changes

2.4 Secondary outcome best corrected visual acuity and cystoid macular edema

A complete routine ophthalmic examination was carried out with special reference to OCT for the fovea and macula. Measurement of CFT and CME was done by OCT pre-operatively, post-op 1 week, 1 month, and 3 months, and BCVA was assessed using logmar.

2.5 Statistical analysis: Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables were presented as mean SD or median (IQR) for non-normally distributed data. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using the Student's t-test. Nominal categorical data between the groups were compared using the Chi-squared test or Fisher's exact test as appropriate. Non-normal distribution continuous variables were compared using Mann Whitney U test. For all statistical tests, a p-value less than 0.05 was taken to indicate a significant difference.

Results: The mean age of the diabetic patients was 64.87 ± 5.15 years and the mean age of non-diabetic patients was 62.87 ± 6.17 . There was no statistically significant difference in the age distribution among the two groups ($p=0.954$). The respective sex distributions in the two groups (male: female) were: group1=17(56.67%):13(43.33%), and group2=19(63.33%):11(36.67%); p value= 0.598 with no statistically significant difference. Out of 30 patients, 4 patients (13.33%) were on diet control, 8 patients (26.67%) were on insulin and 18 patients (60%) were on oral hypoglycemic agents. Visual acuity of the diabetic patients was assessed and pre-op BCVA was compared with post-op BCVA (1 week, 1 month, and 3 months) and was found to be statistically significant in visual improvement (p -value <0.0001) without consideration of OCT findings. Visual acuity of diabetic patients remained the same at 1 week, 1 month, and 3 months postoperatively and was found statistically insignificant (p -value <0.402) (Table 1).

CFT of the diabetic and non diabetic patients was assessed and pre-op CFT was compared with post-op CFT (1 week, 1 month, and 3 months) and was found statistically significant (p -value <0.0001) (Table 2).

CFT of post-op 1 week, 1 month, and 3 months in the diabetic group were compared and overall was found to be statistically significant (p -value <0.0001) (Table 3).

The visual acuity of the diabetic patients who developed CME was assessed. Post-op BCVA was compared with pre-op BCVA and was found to be statistically significant in visual improvement (p-value .001). Still, when post-op BCVA was compared among 1 week, 1 month, and 3 months, the difference was found to be statistically insignificant (p-value <0.245). CFT of the diabetic patients who developed CME was assessed and we found post-op CFT increased significantly from 1 week to 1 month (p=0.019) but there was an insignificant decline from 1 month to 3 months (0.439).

Visual acuity of the non-diabetic patients was assessed and when pre-op BCVA was compared with post-op BCVA we found significant improvement in visual acuity (p-value <.0001) without consideration of OCT findings and when post-op BCVA was compared among 1 week, 1 month and 3 months, there was an insignificant change of BCVA at 3 months (p value <.662) (Table1). CFT of the non-diabetic patients was assessed and pre-op CFT was compared with post-op CFT (1 week, 1 month, and 3 months) and we found an increase in CFT till 1 month followed by a significant decline at 3 months (p value <.0001) (Table2). When CFT of post-ops in non-diabetic patients was assessed, we found a significant increase from 1 week to 1 month (p-value <.0001) and a significant decline from 1 month to 3 months (p value < 0.0001) (Table 3). Visual acuity of non-diabetic patients who developed CME was assessed and post-op BCVA was compared with pre-op BCVA, we found statistically significant improvement in visual acuity (p-value 0.04) and when they were compared among 1 week, 1 month, and 3 months there was a statistically insignificant difference (p-value 0.074). CFT of the non-diabetic patients who developed CME was assessed and post-op CFT increased significantly from 1 week to 1 month (p value 0.007) and also from 1 month to 3 months (p value 0.031).

When the visual acuity of diabetic and non-diabetic post-op patients were compared over the following period, they were found to be statistically insignificant. (Figure1)

However, when CFT was compared, it was found to be statistically significant. (Figure2)
CME was more in diabetic patients (46.67%) significantly as compared to non-diabetic patients (16.67%) (Table 4).

Discussion:

Cataract is the most common clinical problem found in old age and India is no exception. Both type 1 and type 2 diabetes are seen in our country with increased incidence of cataracts. An increasing number of diabetic patients with cataracts are being operated every day.

Complications of cataract surgery with present technology have become less common to almost non-existent except in diabetic patients where there is increased progression of retinopathy, diabetic macular edema, fibrinous uveitis, posterior capsular opacification, etc.^{18,19}

CME is a well-known complication following uncomplicated cataract surgery.^{4,20-22}

In our study, the mean age of diabetic and non-diabetic patients was in the range of 51- 76 years with no statistical significance. So was the analysis of sex in both groups.

The percentage of insulin-dependent diabetic patients was 26.67% in our study.

OCT allows us to correlate BCVA, CFT, and CME.

CFT showed a statistically significant increase after cataract surgery as compared to pre-op CFT in diabetic patients. This agrees with studies done by Kim SJ et al¹⁷ in 2007 but Giocanti-Aurégan A²³ in 2012 found no significant increase in CFT at 3 months after cataract surgery.

Similarly, CFT showed a statistically significant increase after cataract surgery as compared to pre-op CFT in non-diabetic patients. This is in agreement with the studies done by Perente I et al¹⁸ in 2007 but a study conducted by Katsimpris JM et al²⁴ in 2012 showed that there was no significant difference found in CFT of pre-op and post-op patients in the non-diabetic group.

In our study, a significant increase in CFT was seen among diabetic patients when 1 week was compared to 1 month (p-value 0.001), but there was an insignificant decline in CFT from 1 month to 3 months (p 0.067) (Table 2). In nondiabetic patients, there was a significant increase in CFT from 1 week to 1 month and a significant decline from 1 month to 3 months (p value <0.001) (Table 2). Although in both diabetic and non-diabetic patients, an increase in CFT was maximally noted at 1-month post-op and a decline in CFT at 3-month interval which was insignificant in diabetic patients and significant in non-diabetic patients. (Figure 1)

The increase in foveal thickness was significant at the end of 1 month but during the period under study which was 3 months, CFT regressed again but did not return to original levels in both groups (Figure1). Katsimpris JM et al²⁴ in 2012 found that post-op CFT did not return to pre-op values at 3 months in diabetic patients similar to our study. Contrary to our study, Katsimpris JM et al²⁴ said that in nondiabetic patients, CFT regressed to original levels at 3 months. Visual acuity of diabetic and non-diabetic post-op patients was compared up to 3 months after surgery but no significant difference was

found. But CFT of diabetic and non-diabetic patients were compared during the same period and found to be statistically significant as concluded by Katsimpris JM et al²⁴ in 2012.

CME is a well-known complication following uneventful cataract surgery. It is usually transient and self-limiting. The incidence of CME in our study was 46.67% in diabetics and 16.67% in non-diabetic patients (Table 4) but the incidence of CME in the healthy population has been reported to be 9-14% and 31-81% in diabetic patients. Kim SJ et al¹⁷ in 2007, found CME in only 22 % of diabetic patients. However, in non-diabetic patients, CME was detected in 14% by Kim SJ et al¹⁷ in 2008 and 5% by Vukicevic M et al²⁵ in 2012. A significant improvement was seen in BCVA when post-op BCVA was compared to pre-op BCVA in diabetic patients with a p-value of 0.001 and nondiabetic patients with a p-value of 0.042 but an insignificant difference in BCVA was seen among post-op diabetic patients (p-value 0.245) and postop nondiabetic patients (p-value 0.074) was seen despite a significant rise in CFT in both groups.

Our study highlights a higher incidence of increase in thickness following uncomplicated cataract surgery both in the diabetic and non-diabetic group but clinically visual acuity at the end of 3 months was the same in both the groups without any statistical significance which may be because the increase in central foveal thickness was more at a subclinical level which did not give rise to a significant change in visual acuity.

In one diabetic patient, CFT increased from 289 μ m to 427 μ m at one month post-op and at three months was 331 μ m. There is every possibility that a significant increase in foveal thickness in this particular patient might indicate that this patient might develop retinopathy in the future and require regular follow-ups and may one day become an important parameter for prediction of diabetic retinopathy.

CME was seen more in diabetic patients compared to non-diabetic and the difference was statistically significant. Also in patients with CME, there was not much decline in vision by the end of 3 months.

At last, we conclude that diabetic patients are more prone to an increase in central foveal thickness post cataract surgery as compared to non-diabetic patients without hampering BCVA which may be because the changes in CFT were at the subclinical level which did not affect BCVA. Thus, OCT is a non-invasive tool to detect subclinical CME and we may use it to prevent its progression to clinical CME.

A further randomized clinical trial with long-term follow-up is the need of the day.

Table1:

Diabetic	Sample size	Mean \pm Stdev	Median	Min-Max	Inter quartile Range	P value	1 w vs 1m	1 w vs 3 m	1m vs 3m
POD 1W CFT	30	241.1 \pm 18.65	240	211-298	230 - 252	<.0001	0.001	0.006	0.067
POD 1 M CFT	30	257.07 \pm 36.16	253	217-427	241 - 264				
POD 3M CFT	30	249.9 \pm 24.59	249	212-336	232 - 261				
Non Diabetic	Sample size	Mean \pm Stdev	Median	Min-Max	Inter quartile Range	P value	1 w vs 1m	1 w vs 3 m	1m vs 3m
POD 1W CFT	30	233.33 \pm 16.47	226.5	215-274	222 - 239	<.0001	<.0001	0.22	<.0001
POD 1 M CFT	30	240.6 \pm 17.1	236	216-280	230 - 249				
POD 3M CFT	30	234.43 \pm 16.08	230	212-272	222 - 239				

Table 2:

Diabetic	Sample size	Mean \pm Stdev	Median	Min-Max	Inter quartile Range	P value
13 <u>PRE OP CFT</u>	30	234.5 \pm 18.51	233	205-289	220 - 244	
POD 1W CFT	30	241.1 \pm 18.65	240	211-298	230 - 252	<.0001
POD 1 M CFT	30	257.07 \pm 36.16	253	217-427	241 - 264	<.0001
POD 3M CFT	30	249.9 \pm 24.59	249	212-336	232 - 261	<.0001
<u>Non Diabetic</u>	Sample size	Mean \pm Stdev	Median	Min-Max	Inter quartile Range	P value
<u>PRE OP CFT</u>	30	227.53 \pm 17.22	222.5	205-266	216 - 234	
POD 1W CFT	30	233.33 \pm 16.47	226.5	215-274	222 - 239	<.0001
POD 1 M CFT	30	240.6 \pm 17.1	236	216-280	230 - 249	<.0001
POD 3M CFT	30	234.43 \pm 16.08	230	212-272	222 - 239	<.0001

Table 3:

Diabetic	Sample size	Mean \pm Stdev	Median	Min-Max	Inter quartile Range	P value	1 w vs 1m	1 w vs 3 m	1m vs 3m
POD 1W CFT	30	241.1 \pm 18.65	240	211-298	230 - 252	<.0001	0.001	0.006	0.067
POD 1 M CFT	30	257.07 \pm 36.16	253	217-427	241 - 264				
POD 3M CFT	30	249.9 \pm 24.59	249	212-336	232 - 261				
<u>Non Diabetic</u>	Sample size	Mean \pm Stdev	Median	Min-Max	Inter quartile Range	P value	1 w vs 1m	1 w vs 3 m	1m vs 3m
POD 1W CFT	30	233.33 \pm 16.47	226.5	215-274	222 - 239	<.0001	<.0001	0.22	<.0001
POD 1 M CFT	30	240.6 \pm 17.1	236	216-280	230 - 249				
POD 3M CFT	30	234.43 \pm 16.08	230	212-272	222 - 239				

Table 4:

			Total	P value
	Diabetic	Non-Diabetic		
14 CME Negative	53.33%	83.33%	41 (68.33%)	0.012
POSITIVE	46.67%	16.67%	19 (31.67%)	
Total	30 (100.00%)	30 (100.00%)	60 (100.00%)	

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