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Original Research Article

Comparative study of optical coherence tomographic analysis of macula in preoperative and postoperative diabetic patients undergoing small incision cataract surgery

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ABSTRACT

Background: The clinical evaluation of macular edema has been difficult to characterize, but evaluation has become more precise with the help of optical coherence tomography (OCT). This study is undertaken to evaluate the quantitative changes in macular thickness using spectral domain OCT in diabetic patients undergoing cataract surgery pre and post operatively and its relation with diabetic retinopathy (DR).

Materials and Methods: Study participants included 65 diabetic patients irrespective of presence or absence of retinopathy who underwent cataract surgery. Each eye underwent fundus examination with indirect ophthalmoscopy and OCT of macula i.e.,preoperatively and at postoperatively at day 1, 1 week, 4 weeks and at 12 weeks. Best-corrected visual acuity (BCVA) was recorded at each visit.

Results: The central subfield macular thickness (CSMT) increased in all patients irrespective of presence or absence of diabetic retinopathy of about 17.4±25.3μm and 29μm±38.8 at 1 month and 3 month follow up.

Conclusion: There was a statistically significant increase seen in CSMT after cataract surgery especially in patients with preoperatively diagnosed macular edema. Associated retinopathy also acts as a risk factor. But there was no statistically significant increase in mild and moderate NPDR preoperatively and also in postoperative period after uncomplicated small incision cataract surgery.

1. Introduction

In India, an estimated 32 million persons had diabetes in 2000, and roughly 79 million will be affected by 2030. If the prevalence of complications remains unchanged, approximately 0.7 million Indians will have proliferative diabetic retinopathy and 1.8 million will have clinically significant macular edema.[1] Cataract is a common cause of visual impairment in patients with diabetes. Chronic hyperglycemia leads to the production of advanced glycation end products, increased oxidative stress, and increased activation of the polyol pathway, each of which has been implicated in the development of cataracts. As a result, cataract develops and progresses more frequently, rapidly and at an earlier age in patients with diabetes.[2] The risk of cataract development in DM is fivefold higher than in the general population.[3]

Cataract surgery is indicated when the visual function is significantly reduced as a result of the lenticular opacity or if the cataract reduces the view of the retina, thus impeding the diagnosis and treatment of diabetic retinopathy

Cataract surgery is known to cause increased levels of inflammatory mediators. Clinical studies are inconclusive as to the effect of cataract surgery on the onset of diabetic macular oedema (DMO).[4]

Macular oedema (ME) occurs in a variety of pathological conditions and accounts for different degrees of vision loss. Early detection of ME is therefore critical for diagnosis and

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management.

A higher incidence of ME after cataract surgery is reported to occur in eyes with diabetic retinopathy (DR), and worsening of ME often occur after surgery in eyes with pre-operative diabetic macular edema (DME).[5]

In diabetic macular edema (DME), ME is induced by hyperglycemia-induced oxidative stress, deposition of advanced glycation end products (AGES), impaired blood flow, hypoxia, pericyte loss, endothelial cell loss, up regulation of vesicular transport, down regulation of glial cell–derived neurotropic factor and inflammation.

Where as in Pseudophakic cystoid macular edema (PCME), which is thought to be caused by Proinflammatory cytokine release.

OCT is a method of analysing the in-vivo retinal architecture. It is particularly useful and accurate for measuring retinal nerve fibre layer (RNFL) thickness and macular thickness. This study is undertaken to evaluate the quantitative changes in macular thickness using spectral domain optical coherence tomography in diabetic patients undergoing cataract surgery pre and post operatively and its relation with diabetic retinopathy.

2. Materials and Methods

2.1. Study design

It was a prospective comparative study.

2.2. Sample size

65 patients.

2.3. Duration

One and half years.

2.4. Inclusion criteria

All Type 2 diabetic patients irrespective of duration of diabetes of age group 55-75 years with senile immature cataract with varying levels of retinopathy including absence of retinopathy underwent uncomplicated small incision cataract surgery done by an experienced surgeon were included in the study.

2.5. Exclusion criteria

1. Diabetic patients where pre-op OCT is not possible
2. Subluxated lens
3. Pseudo exfoliation
4. Glaucoma
5. Intraoperative any complication
6. Diabetic patients with prior intraocular surgery in the same eye
7. Uveitis
8. Presence of any retinal or choroidal disease, other than diabetes, that could affect retinal thickness.

2.6. Preoperative evaluation

1. Visual acuity testing for distance and near using Snellen's distant chart and near vision chart respectively.
2. Refraction and correction where ever required.
3. External ocular examination
4. Slit lamp bio microscopic examination done with dilated pupilr
5. Tonometry using applanation tonometer
6. Lacrimal patency test
7. Keratometry
8. A-scan and Intraocular lens power calculation by SRK-2 formula
9. Fundus examination with indirect ophthalmoscopy with 20D Lens after dilatation. The level of diabetic retinopathy was recorded as No, mild, moderate, and severe non proliferative; or proliferative, as described in the early treatment diabetic retinopathy study.

Other investigations included: RBS, FBS, PPBS, HBA1C.

Optical coherence tomography testing was done preoperatively and repeated at the POD day1, POD1 week, and 4th and 12th week postoperative visits. Best-corrected visual acuity (BCVA) was recorded at each visit.

Fundus photographs of retina were taken with CANON CF-1 Digital retinal camera. Optical coherence tomography (ZEISS CIRRUS HD-OCT 5000, Carl Zeiss Meditec Inc., and Dublin, CA, USA) testing was performed and images were generated with the use of Macular cube 512*128 in 6 mm square grid according to the manufacturer protocol as described in the user's manual. CIRRUS software identifies the Fovea location automatically by looking for the reduced reflectivity below the retina. We can also change the Fovea location manually which will update the data table and the ETDRS grid thickness measurements. Macular Thickness OU Analysis provides interactive scan images, as well as the Fundus image with a scan cube overlay for both eyes together and includes:

1. Colored thickness maps.
2. OCT Fundus image, including the identified fovea location with a red dot.
3. The ETDRS grid maps with normative data.
4. A table containing central subfield thickness, average thickness and volume Measurements for the entire cube taken.

2.7. Statistical analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean± standard deviation (SD) were used. For categorical data, the

number and percentage were used in the data summaries and diagrammatic presentation. Chi-square ($\chi 2$) test was used for association between two categorical variables.

If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23 (IBM Statistics, Chicago, USA) and Microsoft office 2007.

3. Results

Out of 65 patients 4 were lost to follow-up. 2 patients in the DR group had pseudophakic bullous keratopathy, did not appear for examination because of hazy media. Therefore, 59 patients (90.7%) completed the 3 months follow-up and were included for analysis. The mean age of the study population was 66.0 ±7.8years. Among the 59 patients 36 patients (61%) were males and 23 (39%) were females. Among the 59 study group patients of type II diabetes mellitus patients, most of the patients are with DM ≤5 Years duration of about 67.8% patients. Mean Age duration of DM is 4.8±2.9 yrs. 32 patients (54.2%) were systemic hypertensives.

Right eye cataract surgery was performed in 29 patients and left eye cataract surgery was performed in 30 patients.

No Diabetic retinopathy was detected preoperatively in 44% of diabetic eyes. 18 patients had Mild NPDR which comes to 30.5% of diabetic patients 8 patients had Moderate NPDR comprises 13% of diabetics. Severe NPDR With macular edema in 1 patient and pre op macular edema is seen in 2 patients. (Graph 2)

Preoperatively 93% patients had a vision of 6/60 or lesser. Over all visual acuity improved postoperatively at 4th and 12th week after small incision cataract surgery to 6/12 and 6/9 in majority of the patients. Post operatively 1 month 75% patients achieved vision of 6/6– 6/12. By Post-operative 3 months 89.8% patients achieved a vision of 6/6 – 6/12.(Graph 3)

Mean central subfield macular thickness on OCT in diabetic patients of all grades of DR is increased with higher statistical significance at 1 and 3 months post operatively compared to 1st week postoperatively.

The central subfield mean thickness in all patients irrespective of diabetic retinopathy increased 17.4μm and 29μm at 1 month and 3 months follow up. A statistically significant increase could be detected in central subfield macular thickness though the increase was mild. (P<0.002) Mean Pre op CSMT of all patients is 267.6±16.9μm. Mean Central subfield thickness increased from 267±16.9μm to 285±42.2 at 1 month and to 296.6±55.7μm at 3 month follow up with P-valve 0.002*(p<0.05) among all the diabetic cases.(Graph 4)

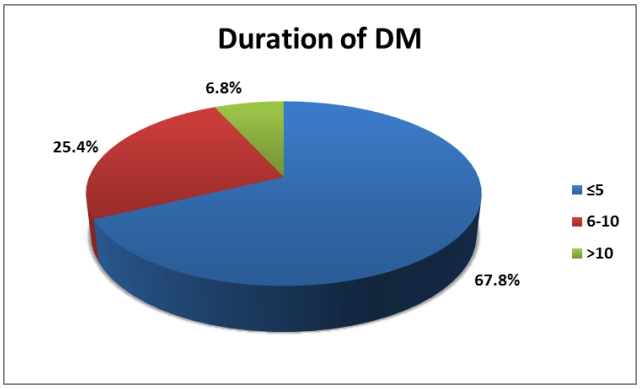
In this study, level of diabetic retinopathy was associated with increased foveal thickening. The study group with no diabetic retinopathy developed increases in foveal thickening, of 15.2 um and 21.2 um at 4th and 12th week after surgery, respectively. Among patients with no diabetic retinopathy developed thickening from a preoperative mean value of 255.9±12.0 to 277.1±12.2μm at 3rd month of follow up with a P-value of 0.030*(p<0.05). The worse the level of diabetic retinopathy at baseline, the more likely the foveal thickness increased at 4th and 12th week after surgery. The group with mild non proliferative diabetic retinopathy had increase in center point thickness—of 4.4um and 8.4 um at 4th and 12th week after surgery respectively with low level of significance. But it is not statistically significant in mild and moderate NPDR cases due to small number of patients. The group with moderate non proliferative diabetic retinopathy with macular edema had largest increase in foveal thickness 57.5um and 136 um at 4th and 12th week after surgery respectively. This increase in foveal thickness was correlated inversely with VA improvement.

In eyes with preoperative moderate NPDR with macular edema the mean change of central subfield macular thickness was 136μm at 3 months follow up. (P value - 0.044).

The patients who developed macular edema had decrease in visual acuity.

In eyes with preoperative macular edema the mean change of central subfield macular thickness was 27μm at 3 months follow up.

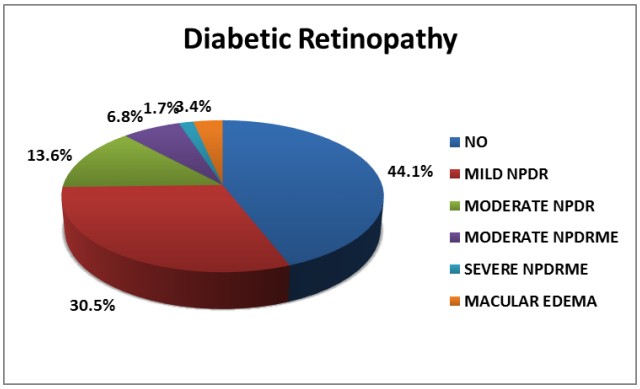
Severity of DR was not significantly correlated to ME because of limitation in sample size. No statistical difference in macular thickness was revealed through severity of DR.



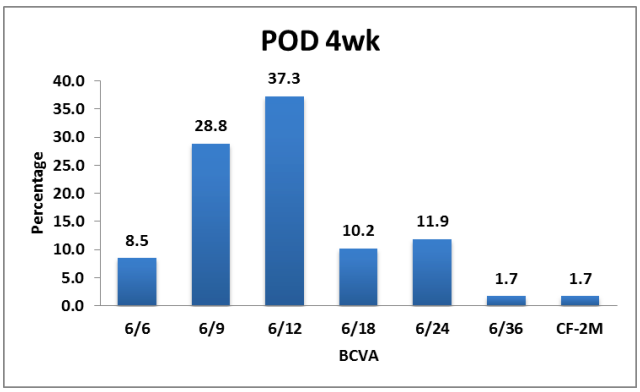
Graph 1: Distribution of cases according to duration of DM

Mean values of central subfield macular thickness in microns.

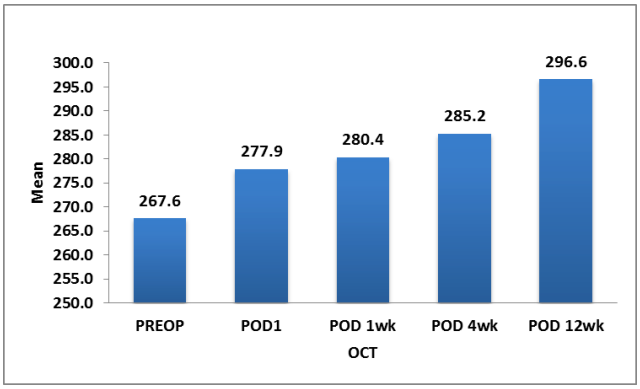
This is a graph showing mean value of OCT central subfeild macular thickness (CSMT) in micrometers (μm) which is at preoperatively 267.6μm increased to 277.9μm at postoperative day1, 280.4μm at postoperative 1 week, 285.2 μm at postoperative 4 weeks and 296.6μm at postoperative



Graph 2: Distribution of cases according to diabetic retinopathy



Graph 3: Distribution of cases according to BCVA at POD 12wk



Graph 4: Distribution of OCT according to Pre and post operative among all cases

12 weeks. Y Axis showing the mean value of CSMT, X-axis showing pre and postoperative duration

The mean ±SD in microns foveal thickness in all the patients groups are shown in and Table 1 and Graph 4, respectively.

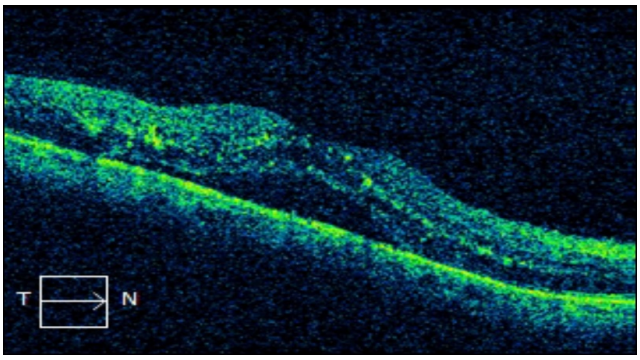


Fig. 1: Serous retinal detachment at 12th week

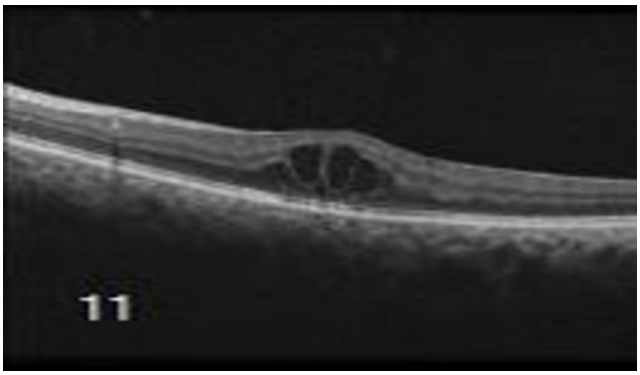


Fig. 2: Cystoid macular edema of a patient at 3 months of F/UP

4. Discussion

The macular thickness in diabetic patients with and without DR was increased significantly at the end of the fourth week postoperatively compared to the preoperative results. This thickening persisted until 12 weeks postoperatively in all subjects and did not regress to preoperative levels till the last follow-up at 12 weeks. This study demonstrated that the influence of uncomplicated cataract surgery on CSMT in diabetic patients without diabetic retinopathy did not significantly differ from patients with diabetic retinopathy who are undergoing cataract surgery.

In this study OCT has been able to demonstrate a moderate correlation between retinal thickness and best-corrected visual acuity, and it has been able to demonstrate 3 basic structural changes of the retina, i.e., diffuse retinal swelling, cystoid macular edema, and serous retinal detachment.

Table 1: Distribution of OCT according to POD among all cases

Total cases	PREOP		POD1		p value
	Mean	SD	Mean	SD	
	267.6	16.9	277.9	43.5	0.039*
	POD1		POD 1wk		p value
	277.9	43.5	280.4	38.5	0.321
OCT central sub field thickness	POD 1wk		POD 4wk		p value
	280.4	38.5	285.2	42.2	0.029*
	POD 4wk		POD 12wk		p value
	285.2	42.2	296.6	55.7	0.002*

Note: * significant at 5% level of significance (p<0.05)

Most of the studies in the literature showed[6–8] that mean CMT is statistically significant increase at 1 month after cataract surgery, which was maintained after 3 months, pointing out a possible leakage. Also, baseline CMT was thicker in eyes developing PCME, suggesting that increased CMT thickness may be a predisposing factor for Pseudophakic Cystoid Macular Edema(PCME) or the presence of subclinical PCME, which may not be detected by OCT imaging systems. This is witnessed in one of our patients. Inflammatory mediators may increase vascular permeability leading to an increase in macular thickness and cyst formation.[9–11] Now a day's use of SD-OCT provides quicker, more objective, and noninvasive assessments of retinal thickness compared to FA. Compared to time-domain OCT, SD-OCT offers more accurate measurements, higher repeatability, and a lower rate of errors and false-negatives.

Duker et al. showed that SD-OCT has enabled ophthalmologists to visualize and monitor the vitreomacular interface with better accuracy and repeatability.[12]

Mentes et al. found that Angiographic CME was seen in 9% after cataract surgery using fluorescein angiography in people without diabetes.[13]

Romero- Aroca et al. reported that 6.06% of 132 eyes of diabetic patients developed DME on evaluation by fluorescein angiography and OCT following uneventful phacoemulsification.[14]

Hayashi et al. have shown that the foveal thickness and macular volume in diabetic patients increases after small incision cataract surgery in eyes both with and without DR: the percent increase from baseline was greatest at 3 months after surgery, and then decreased gradually.

Furthermore, the increase in foveal thickness was greater in eyes with DR than in eyes without DR. These results indicate that, on average, diabetic macular oedema worsens after cataract surgery, and the worsening is more pronounced in eyes with DR.[15]

This study showed similar significant correlation between level of retinopathy, foveal thickness but the current study is limited by the duration of follow-up of patients to know the maculopathy progression or regression as described by hayashi.

Alastair K Denniston, Usha Chakravarthy et al. reported that rate of developing treatment-requiring DMO increases sharply in the year after cataract surgery for all grades of retinopathy, peaking in the 3–6 months' postoperative period. Patients with moderate and severe NPDR are at particularly high risk.[4]

We found that the Mean macular foveal thickness preoperatively, 1 week, 1 month and 3 months postoperatively in diabetic patients with diabetic retinopathy (mild, moderate and severe NPDR) was not statistically higher compared to patients without DR. but overall irrespective of DR macular thickness is increased There is improvement in visual acuity after 1 and 3 months postoperatively in patient with no DR than those with DR. this finding is consistent with the fact of deficient blood retinal barrier function in those patients with more advanced vascular changes resulting from DR.[16] Many previous studies[17] showed the high risk of developing macular edema in patients with diabetic retinopathy but most of the studies included the patients with preoperative high macular thickness like ours. But the patients with increased macular thickness are less in our study (10%) to prove it is statistically significant.

Kim et al[18] found that there is threshold of increase in macular thickening post cataract surgery which associated with clinically impaired visual outcomes. An increase of 40% or more in macular thickness[18] or a morphological Irvine-Gass pattern of cystic changes as detected by OCT[19] could be regarded as a threshold for reporting clinical vision-relevant post cataract macular edema.

In our study, there was no difference in median macular thickness between the groups, and no cases in either group had an increase in macular thickness to reach this threshold. We thus believe that the increases in macular thickness in all of our cases could only be regarded as subclinical changes.

In conclusion, we have demonstrated that the diabetic macular edema generally worsens after cataract surgery, and that the worsening of macular edema is more prominent in eyes with DR. and the change in patients without diabetic retinopathy is subclinical without affecting the visual acuity.

Therefore by analysing macula using OCT in our study we were able to diagnose minimal edema at earliest, we can

conclude that OCT plays a major role in earlier management and visual acuity recovery in diabetic patients undergoing cataract surgery.

To provide patients with DR the benefits of cataract surgery and avoiding the progression of macular edema it is advised that all patients with DR should be evaluated with OCT, particularly in the early postoperative period to detect macular changes, so that early diagnosis timely adequate management can be ensured.

The limitations to this study are small sample size in sub group of patients with varying levels of diabetic retinopathy.

Another major limitation is that we did not compared the long term macular changes and the visual results.

5. Conclusion

Mean central subfield macular thickness on OCT in diabetic patients of all grades of DR is increased with higher statistical significance at 1 and 3 months post operatively compared to 1st week post operatively. The central subfield mean thickness in all patients irrespective of diabetic retinopathy increased 17.4μm and 29μm at 1 month and 3 month follow up. A statistically significant increase could be detected in central subfield macular thickness though the increase was mild. (P<0.002). Eyes with preoperative macular edema after cataract surgery are high risk of developing macular edema.

All diabetic patients need close observation for at least 6 months following surgery to intervene with laser photocoagulation and anti VEGF as and when required to prevent visual loss from diabetic maculopathy and other consequences of diabetic retinopathy.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare that there is no conflict of interest.

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