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A Study on Changes in Macular Thickness after Cataract Surgery in Diabetic Patients Using Optical Coherence Tomography (OCT)

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Abstract: ***Aim: To assess the macular thickness changes after cataract surgery in diabetic patients using optical coherence tomography (OCT). Materials and methods: In this Prospective study, a total of 150 patients divided into three equal groups (Group 1 included non-diabetic patients, Group 2 included diabetic patients without retinopathy and group 3 included patients with diabetic retinopathy) were operated for cataract by manual Small Incision Cataract Surgery (m-SICS). Complete ophthalmological evaluation was done preoperatively. Patients were followed at day 1 post operation and at 2, 6 and 12 weeks postoperatively. At each visit a complete ophthalmic evaluation and optical coherence tomography of the macula were performed. Results: There was significant increase in foveal thickness at 6 weeks in diabetics with retinopathy as compared to those without retinopathy and controls. 26% of diabetics developed macular edema as compared to 4% in controls. Conclusion: Post operative change in macular thickness and visual outcomes depends significantly on the diabetic status, duration and retinopathy levels. A positive correlation was also found between change in macular thickness and HbA1C levels in diabetic patients.***

Keywords: Diabetic retinopathy, Small Incision cataract surgery, Optical coherence tomography

1. Introduction

Macular edema is one of the most common causes of visual loss after uncomplicated cataract surgery.[1, 2] Diabetes has been associated with an increased incidence of postoperative macular edema. The incidence of macular edema on optical coherence tomography (OCT) was 22% in diabetic eyes undergoing cataract surgery.[3] It is hard to differentiate the cause of macular edema after cataract surgery in diabetic patients as it could be caused by the cataract surgery or diabetes itself.

Cataract surgery induced surgical trauma resulting in prostaglandins release and blood retinal barriers disruption is thought to be the cause of macular edema.[4,5] Other causes could be vitreo-macular traction and light induced toxicity.[6,7]

OCT has been shown to be highly reproducible in measuring macular thickness in normal individuals and diabetic patients.[8,9] As OCT can assess macular thickness quantitatively, it can detect subtle changes of macular thickness and is especially useful in mild cases. OCT is found to be as effective as fluorescein angiography.[10]

Considering these, this study was taken up with following purpose:
To assess the macular thickness changes after cataract surgery (m-SICS) in diabetic patients using optical coherence tomography (OCT).

2. Materials and Methods

This prospective, comparative study was designed to assess the clinical outcome of diabetic patients with and without diabetic retinopathy undergoing cataract surgery. This study was conducted during the period of September 2015 to August 2016 in Regional Institute of Ophthalmology, Guwahati (Assam, India). Informed consent was obtained from all patients.

The study enrolled 150 patients divided into three groups: Group 1 included 50 non- diabetic patients while group 2 included 50 diabetic patients without having DR and Group 3 included 50 Diabetic patients having DR. Patients aged between 30-80 years of both sexes with T2DM with or without DR who underwent m-SICS were included as cases while non-diabetic patients were included as controls. Patients with other retinopathies, pre existing glaucoma and those having severe hypertension and nephropathies were excluded.

All patients had clinically significant age related cataract of LOCS III (Lens Opacities Classification System) grade N3, diabetes mellitus type II for the group of diabetic patients, and no diabetes as proved by fasting blood glucose test for the control group.

A detailed ocular and systemic history was taken. Each patient underwent best corrected distance VA (Visual Acuity) measurement with LogMar equivalent of standard Snellen's chart and Snellen's near vision chart for both eyes. All the patients underwent anterior segment examination, biomicroscopic evaluation with fundus non contact +90D lens.

Routine blood and urine investigations along with Glycosylated haemoglobin (HbA1C) were done at presentation.

All patients were prescribed Topical Gatifloxacin 0.3% one day before the surgery along with Topical flurbiprofen sodium 0.03%. On operation day, Topical flurbiprofen

sodium 0.03% was instilled thrice at 10 minute intervals along with topical mydriatics, a combination of two eye drops, 0.8% tropicamide and 5% phenylephrine, thrice at 10-minute intervals was given. All surgeries were done under peribulbar anesthesia by a single surgeon. After sterile preparation, Manual Small Incision Cataract Surgery was performed. Postoperatively, topical flurbiprofen was prescribed along with corticosteroid and antibiotic (Gatifloxacin 0.3% and Dexamethasone 0.1%), both 4 times a day, were prescribed for 6 weeks in all three groups.

Central macular thickness (CMT) was measured with Stratus OCT machine model 3000 (Carl Zeiss Meditec Inc.) with software version 4.0. The Fast macular thickness (FMT) protocol was used. The study parameters were evaluated on pre operative day which was taken as baseline. A 30% increase in foveal thickness from baseline (Pre operative) was considered as macular edema.

Patients were followed up at day 1, 2 weeks, 6weeks and 12 weeks post surgery. Complete ocular examination including OCT was done on each follow up.

3. Statistical Methodology

The data were presented as the mean ± standard deviation. Statistical differences during follow ups were assessed using a Paired t-test. To find correlation between the variables Pearson's correlation of coefficient was applied. A p-value of less than 0.05 was considered to be statistically significant.

4. Results

A. Demographics

Mean age in three groups were 63.6 ± 7.923 years, 56.06 ± 10.803 years and 62.68 ± 9.813 years respectively. Group 1 had equal representation of male and female patients while there were 28 females and 22 males in both group 2 and 3.

37 participants had ≥ 10 years and 63 participants had < 10 years of diabetic history.

48% patients from group 3 had diabetes of more than 10 years duration while only 28% patients in group 2 had diabetes for more than 10 years.

In group 3, 28 participants had mild NPDR (Non progressive diabetic retinopathy), 12 had moderate NPDR and 10 had severe NPDR. 4(8%) participants showed progression of retinopathy.(Figure 1)

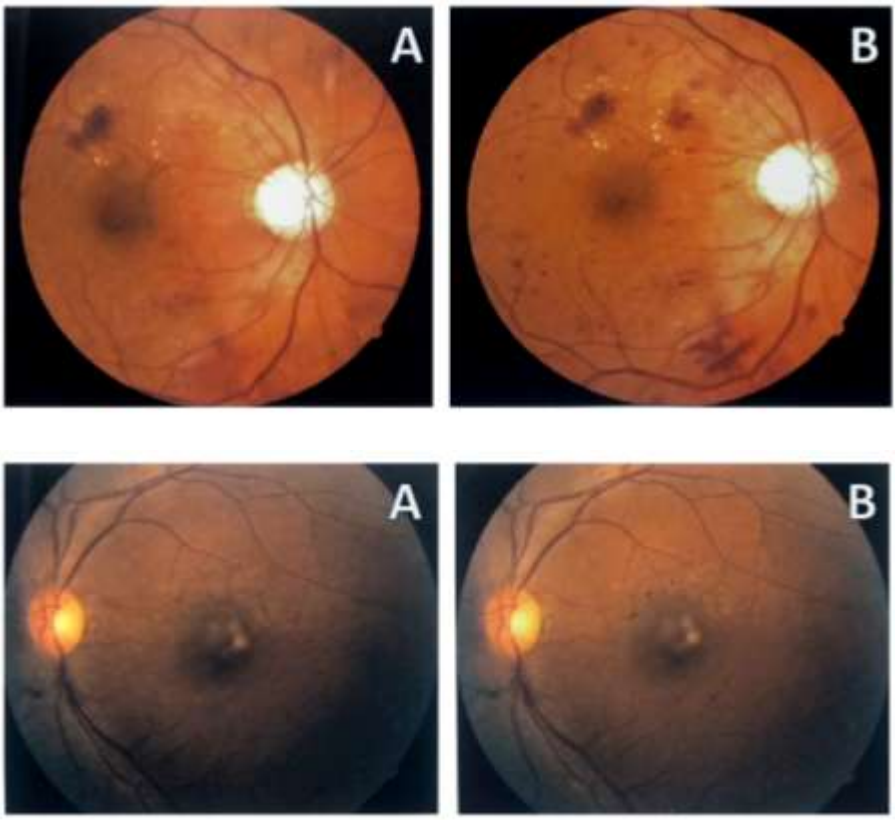

Figure 1: Fundus photographs showing changes in grades of retinopathy from baseline (A) and at 12 weeks (B) in two patients

B. Visual acuity

Visual acuity improved in all three groups. Post operative visual acuity at day one was best in Group 1 patients while it was worse in Group 2 than Group 3. Final visual acuity at 12 weeks was best in Group 1 patients and worse in group 3. **(Table 1 and Figure 2)** Group 2 showed maximum range of improvement in visual acuity in post operative period. **(Figure 3)**

Table 1: Best corrected visual acuity of patients (in LogMar Unit)

	Pre-operative	Day 1	2 weeks	6 weeks	12 weeks
Group 1	1.225 ± 0.292	0.207 ± 0.097	0.164 ± 0.121	0.078 ± 0.121	0.012±0.085
Group 2	1.390 ± 0.414	0.415 ± 0.155	0.195 ± 0.191	0.153 ± 0.196	0.09±0.161
Group 3	1.347 ± 0.323	0.227± 0.104	0.252± 0.118	0.36± 0.1607	0.185±.161

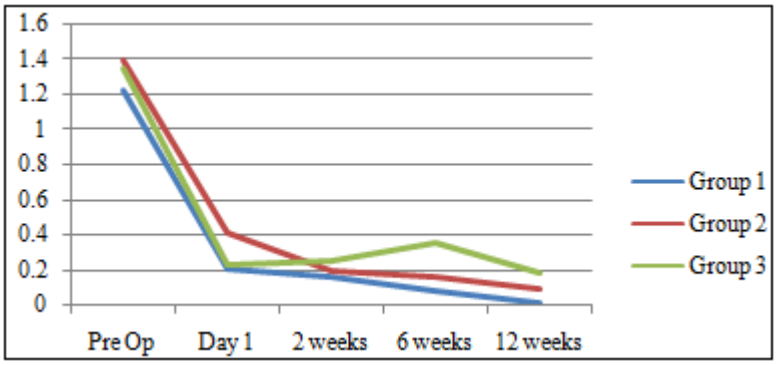

Figure 2: Best corrected visual acuity of patients (in LogMar Unit)

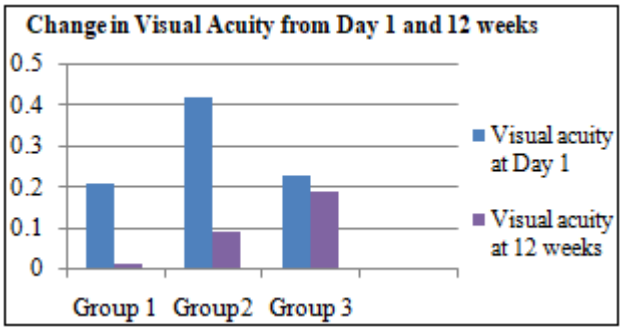

Figure 3: Change in visual acuity from Day 1 and at 12 weeks

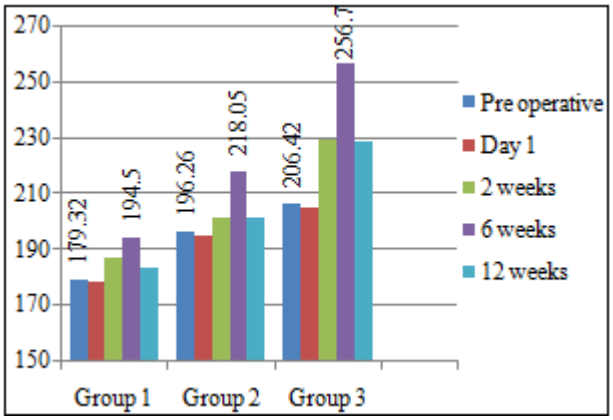

Figure 4: Foveal thickness (µm) in post operative period

C. Changes in foveal thickness (µm) in post operative period:

Post operatively, on day 1, foveal thickness decreased slightly in all three groups but it was not significant (p value >0.5)). Mean increase in foveal thickness in Group 1 was 15.18 µm (p value 0.0010, considered extremely significant) at 6 weeks compared to 21.79 µm in Group 2 (p value 0.0282, considered significant) and 50.28 µm (p value <0.0001, considered extremely significant) in Group 3. [Data comparison done using One Way Analysis of Variance (ANOVA)] **(Table 2 and Figure 4)**

Table 2: Foveal thickness (µm) in post operative period

	Pre Operative	Day 1	2 weeks	6 weeks	12 weeks
Group 1	179.32 ± 18.147	178.32 ±18.220	187.04 ± 19.484	194.5 ± 19.787	183.3 ± 19.717
Group 2	196.26 ± 42.2	194.74 ± 41.526	201.14 ± 41.795	218.05 ± 37.354	201.6 ± 30.354
Group 3	206.42 ± 30.823	205.04 ± 30.647	229.76 ± 33.487	256.7 ± 37.599	228.6 ± 34.309

D. Prevalence of Macular edema

2 (4%) eyes in Group 1, 9 (18%) in Group 2 and 17 (34%) eyes in Group 3 developed macular edema post operatively at 6 weeks. Therefore 26 subjects (26%) out of 100 diabetic subjects developed macular edema post operatively at 6 weeks. **(Figure 5)**

When prevalence of Macular edema was compared in diabetics and non diabetics by Fisher's Exact Test, the two sided p value was 0.0007 which was considered significant. The relative risk was calculated using approximation of Katz as 1.531. While prevalence of macular edema amongst diabetic patients with retinopathy was more than patients without retinopathy but the two sided p value was 0.1095 which was not significant.

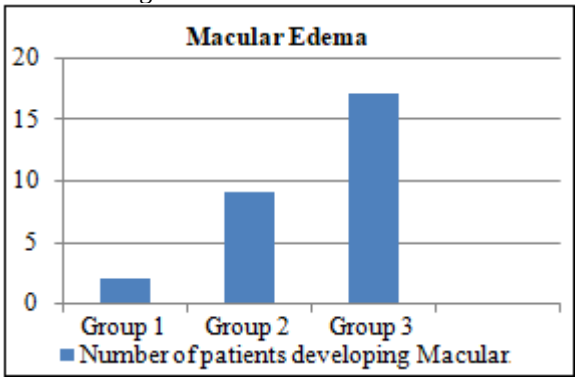

Figure 5: Number of patients developing macular edema

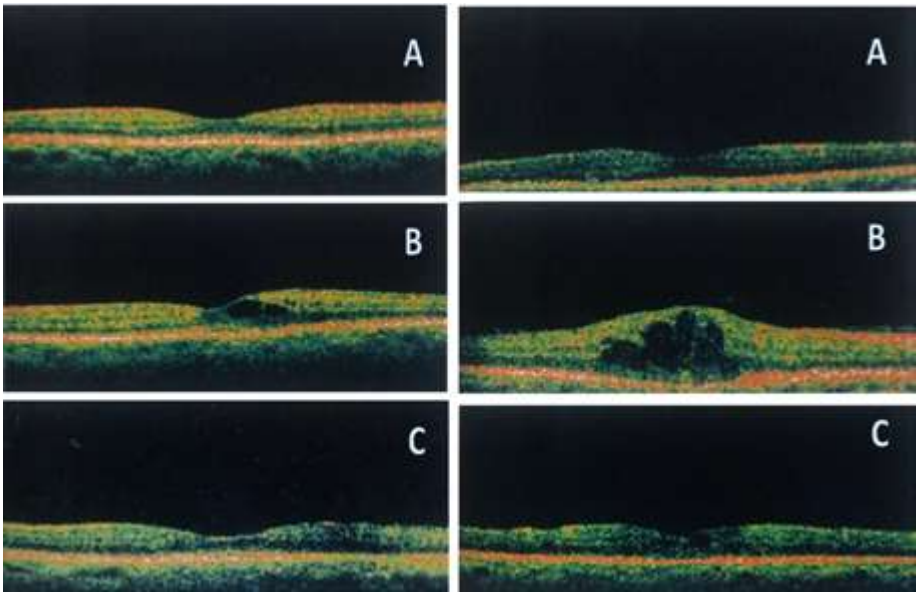

Figure 6: Post operative OCT pictures of two patients at day 1 (A), with cystic changes in fovea at 6 weeks (B) and resolution by 6 weeks (C)

E. Increase in foveal thickness with duration of diabetes

Those with < 10 years duration of diabetes had only 28.9 µm mean increase in foveal thickness while participants with ≥10 years duration of diabetes had mean increase in foveal thickness of 47.9 µm. Repeated Measures Analysis of Variance was performed. The p value was < 0.0001 and considered extremely significant **(Figure 7)**

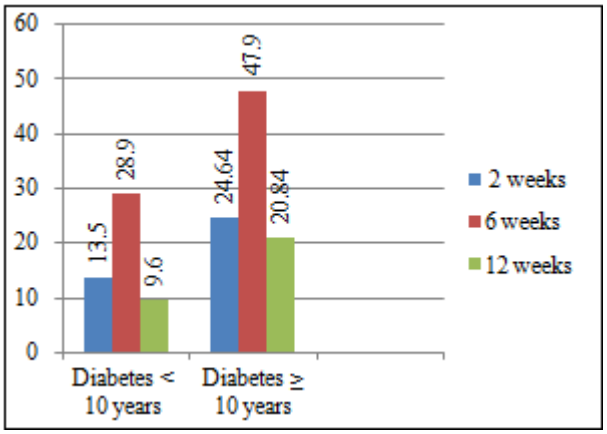

Figure 7: Increase in foveal thickness with duration of diabetes

F. Increase in foveal thickness with grades of retinopathy

There was significant increase in foveal thickness at 6 weeks for those with moderate or severe NPDR (67.6 µm) as compared to those with mild NPDR (36.7 µm). Repeated Measures Analysis of Variance was performed. The p value was < 0.0001, considered extremely significant. (Figure 8)

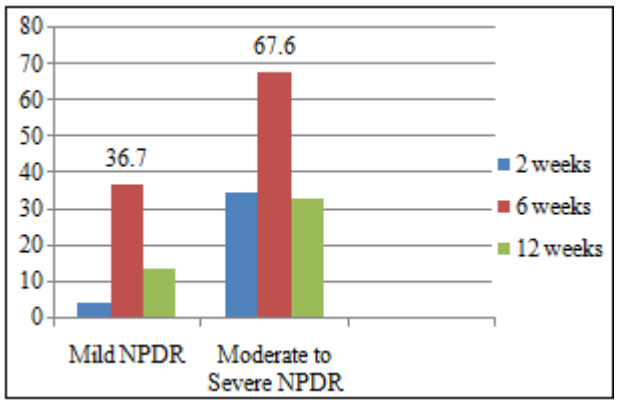

Figure 8: Increase in foveal thickness (µm) with grades of retinopathy

G. Glycosylated Hemoglobin

The mean value of Glycosylated Hemoglobin was 4.75 gm% in Group 1 while it was 8.216 gm% and 8.592 gm % in Group 3 respectively. A positive correlation was found between changes in foveal thickness in OCT and glycosylated hemoglobin in Group 2 (correlation coefficient = 0.5193, p value < 0.0001) and Group 3 patients (correlation coefficient = 0.5627, p value < 0.0001).

5. Discussion

Neumaier-Ammerer B *et al* (2008)[11] studied 25 eyes of 25 patients divided into two groups. Group 1 included 10 patients without any general internal disease while group 2 included patients with diabetes ± hypertension. They found no significant increase of foveal thickness after uneventful phacoemulsification surgery in both groups and there was no significant difference between these groups. However the percentage of eyes with foveal thickening was higher in group 2 than in group 1 (60% to 20% after 4 weeks and 47% to 30% 12 weeks after surgery).

Kwon SI *et al* (2011)[12] studied 104 subjects (36 men and 68 women). The number of patients without diabetic retinopathy were 61 (58.65%), with mild to moderate NPDR

were 27 (25.96%), with severe NPDR or PDR were 16 (15.36%). The most common complication was macular edema, which were occurred in 19 eyes (18.27%), followed by retinopathy progression (11.54%).Among the 19 eyes with macular edema, 12 eyes (63%) developed macular edema at 1 month after surgery, and 13 eyes (68%) showed improvement of macular edema by 6 months after surgery. The remaining 6 eyes did not improve by 6 months.

Gharbiya M *et al* (2013)[13] studied a total of 40 eyes of 40 patients (16 male and 24 female). Average BCVA of the operated eyes was significantly improved with respect to that of the fellow eyes. On the first post-operative day, mean retinal thickness of all macular subfields of operated eyes decreased significantly compared with fellow eyes. CMT of the operated eyes began to significantly increase from the first month after surgery, with a peak at 2 months. At 6 months, retinal thickness of the outer macular area of the operated eyes was still significantly increased whereas there was no significant difference in retinal thickness of the central fovea.

Stunf Pukl S *et al* (2017)[14] studied 28 eyes of 28 patients (10 patients were non diabetic while 18 were diabetic without any diabetic retinopathy). After cataract surgery Mean retinal thickness in the in the diabetic group changed from 238.6 µm preoperatively to 255.2 (p=0.02) 6 months after cataract surgery. In the control group, the thickness in the central field changed from 247.6 µm preoperatively to 261.7 (p=0.03) 6 months after cataract operation.

Wang KY *et al* (2014)[15] studied 58 eyes of diabetic patients and 101 eyes of control patients. The average age of the patients was 67.11 years, and 54.1% were male. There were significant improvements in BCVA at all postoperative examination time periods. In the non-diabetic group, there was a statistically significant increase in CRT at postoperative Week 2 and postoperative Week 4. In the diabetic without retinopathy group, the CRT at postoperative Week 4 increased significantly compared to the baseline value. There were no significant differences in mean CRT and BCVA between the groups preoperatively and at postoperative Week 1, Week 2 and Week 4. There was no statistically significant correlation between CRT and HbA1c or BCVA in logMAR and HbA1c preoperatively, at Week 1, Week 2, and Week 4.

In the present study, average BCVA of operated eyes was significantly improved similar to above mentioned studies. Incidence of macular edema following cataract surgery in diabetic patients was 26% and it was more in Group 3 patients. **Kwon SI** *et al* (2011) [12] found it 18.27%. Foveal thickness of operated eyes decreased on day 1 post surgery similar to **Gharbiya M** *et al* (2013) [13], though was not significant. Further Central macular thickness increased following that and reached its peak at 6 weeks which is in similar with **Gharbiya M** *et al* (2013) [13] where foveal thickness reached its peak at 2 months following surgery and **Kwon SI** *et al* (2011) [12] where 63% macular edema developed at 1 month after surgery. Final CMT at 12 weeks remained higher than that at baseline similar to the above mentioned studies. A positive correlation was also found between changes in foveal thickness in OCT and HbA1C in Group 2 and Group 3 patients.

6. 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. The result of this study suggest that post operative change in macular thickness and visual outcomes depends significantly on the diabetic status, duration and retinopathy levels. A positive correlation was also found between change in macular thickness and HbA1C levels in diabetic patients.

7. Financial Support and Sponsorship

Nil

8. Conflicts of Interest

There are no conflicts of interest.

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