ORIGINAL RESEARCH PAPER

Ophthalmology

"TO STUDY THE CHANGE IN MACULAR THICKNESS POST PHACOEMULSIFICATION AND ITS ASSOCIATION WITH VARIOUS FACTORS"

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ABSTRACT

Context: Macular edema is a common cause of unfavourable visual outcome after cataract surgery. Clinically significant macular edema (CSME) has a reported incidence of 1% to 2% after cataract surgery. OCT has been shown to be highly reproducible in measuring macular thickness in normal individuals and diabetic patients. For detecting macular edema, OCT is superior to contact lens bio microscopy and as effective as fluorescein angiography (FAG). Since OCT can assess macular thickness quantitatively, it can detect subtle changes of macular thickness and is especially useful in mild cases. In this study, we assessed the changes of macular thickness in all patients after cataract surgery using OCT and also examined its co-relation with various parameters like age, gender, cataract grading, diabetic and effective phaco time(EPT).

Aims:
1. To look for the change in pre-operative and post-operative macular thickness using optical coherence tomography.
2. To compare this change with various factors like- vision, age, gender, EPT (effective phaco time), cataract grading and diabetic status of the patient.
3. To look for the factor maximally affecting this change and improve it.

Settings and design: It was a prospective study of 72 patients with cataract undergoing phacoemulsification for cataract extraction, including both diabetics and non-diabetics at Shree Krishna Hospital, Karamsad from July 2019 to August 2020.

Material and methods: After approval from the ethical committee we found out 72 cases according to our inclusion and exclusion criteria and called them for their ophthalmic assessment. All the cases were classified according to their age, gender, diabetic status and cataract grading. Pre-operative visual assessment using Snellen's visual acuity chart and macular thickness assessment was done using optical coherence tomography(OCT). Similarly, post-operative vision and macular thickness was noted. Other factors like age, gender, diabetic status, cataract grading and EPT was noted. The mean age of the study population was 61.85 years (ranging from 40 to 82years). The gender distribution in the study population was found to be of 39 males and 33 females.

Statistical analysis used: STATA 14 was used for analysing the data. Independent sample t test was used to compare the two independent groups for the changes in macular thickness.

Results: Patients undergoing phacoemulsification had no significant co-relationship between the change in macular thickness and age, diabetic status, gender, cataract grading and vision. However, co-relation between EPT and macular thickness change was found. Relationship between Age and EPT was also established.

Conclusion: There is a significant co-relationship of macular thickness change with EPT. However, the sample size is relatively inadequate to prove association with factors.

INTRODUCTION:

The outcome of a successful cataract surgery is based on the technical quality of the procedure and the presence of other ophthalmic diseases or complications pre-operative, intra-operative as well as post-operative.

Macular oedema is a common cause of unfavourable visual outcome post cataract surgery. Although CSME is a very rare cause of visual disability post cataract surgery nowadays, as preventive measures pre-operatively are well taken care of. Diabetes is an associated factor found to be with CSME.

Also other intra-operative factors like EPT also affect the changes in macula. A higher value of EPT signifies that more energy has been used to emulsify the cataract, and hence can induce significant changes over the macula. Age and gender are the few non-modifiable factors which have an irreversible effect on the macular thickness.

To identify the potential cause for decreased visual acuity post cataract surgery in cases of no apparent uneventful phacoemulsification, various tests can be performed depending on the clinical situation at hand. However, amongst them OCT is the least invasive and most accurate investigation offering the most information on the macula. It has been shown to be highly reproducible in measuring macular thickness and measures macular thickness quantitatively and hence can detect subtle changes of thickness and is especially useful in mild cases.

This study aims at detecting changes of macular thickness post phacoemulsification and to look if it has any significant relationship with various factor like age, gender, diabetic status, cataract status and EPT. Also, to find if the macular thickness changes are significant to cause visual disability even after all the pre-operative and intra-operative measures being taken and thus prevent it based on the various factors co-related with it.

MATERIALS AND METHODS:

Study design:

This is a prospective study undertaken at ophthalmology department at a tertiary health care centre affiliated with a medical college after approval of ethics committee of the college.

Study area:

The study was conducted in ophthalmology department of tertiary health centre in western province of India.

INCLUSION CRITERIA:

All patients-males and females, having cataract and

undergoing phacoemulsification at Shree Krishna Hospital irrespective of their choices of foldable IOL are included. It includes both diabetic and non-diabetic.

EXCLUSION CRITERIA:
- Patients already having macular pathology.
- Patients with known cases of CSME/CME
- Patients with hazy media whose OCT is not possible
- Patients with known retinal pathology
- Patients on systemic drugs causing retinal toxicity

Data collection:
Total 72 patients were included in the study. Participants were selected from outpatient department. The study was conducted on all patients with cataract undergoing phacoe-mulsification.

They were briefed about the OCT scanning. Pre-operative visual assessment on Snellen's visual acuity chart along with the routine ophthalmological examination like Goldmann's applanation tonometry, best corrected visual acuity, dilated fundus and slit lamp examination for accurate cataract evaluation was done. Pre-operative fasting and post prandial sugars were checked in cases of diabetic patients and random plasma sugar was checked in all non-diabetics. Drug history was also noted for each patient. Pre-operative antibiotics were started in all patients along with topical NSAIDs- Acular L S eye drops in especially diabetic patients. The EPT was note in the OT setting after phacoemulsification. Post-operatively i.e. on the next day visual acuity, slit lamp examination and OCT scanning was done. The procedure was repeated on 7th and 30th post-operative day. During each OCT scanning macular thickness was noted.

Protection of participants from unanticipated harm arising out of the study: None

Ethical issues: informed consent in English & vernacular language was taken after duly explaining the participants about the study and answering all the questions the participants may have. The consent forms are attached.

STATISTICAL ANALYSIS:
Independent sample t test was used to compare the two independent groups for the changes in macular thickness using the STAT 14 tool.

RESULTS:

The Mean And Standard Deviation Of Important Factors: Table 1

	N	Minimum	Maximum	Mean	Std. Deviation
EPT	72	0	47.30340	15.0993	9.86
PRE OP MT	72	204	340	246.63	25.95
POST OP MT	72	201	300	245.46	20.96
1WK MT	72	210	310	246.76	23.33
1MN MT	72	204	299	247.22	21.99

Relationship Between Change In Macular Thickness With Ept On The First Post-op Day: Table 2

EPT GROUP	CHANGE IN MACULAR THICKNESS FROM BASELINE		
	MEAN	STD. DEV.	FREQUENCY
1	1.478261	26.693325	23
2	0.53125	14.602219	32
3	-8.916667	23.811603	12
4	-6	2.8284271	2
5	-38.66667	44.635561	3
TOTAL	-2.5555556	23.017378	72

Table 3: Relationship Between Change In Macular Thickness With Ept In The First Post-op Week:

EPT	CHANGE IN MACULAR THICKNESS FROM BASELINE		
	MEAN	STD. DEV.	FREQUENCY
1	1.130435	32.027409	23
2	1.125	14.459621	32
3	-3.916667	21.517259	12
4	2.5	2.1213203	2
5	-36.66667	37.753587	3
TOTAL	-1.25	24.084213	72

Table 4: Relationship Between Change In Macular Thickness With Ept In The First Post-op Month:

EPT	CHANGE IN MACULAR THICKNESS FROM BASELINE		
	MEAN	STD. DEV.	FREQUENCY
1	2.173913	28.806018	23
2	0.8125	13.952541	32
3	-1.666667	16.658786	12
4	0.5	3.5355339	2
5	-38	41.327957	3
TOTAL	-0.791667	22.272915	72

Table 5: Correlation Matrix

	Difference in macular thickness at 1st post-op day(Post MT-Pre MT)	Difference in macular thickness at 1st post-op day (Post MT-Pre MT)	Difference in macular thickness at 1st post-op day (Post MT-Pre MT)	EPT	AGE (yrs)	Difference in near vision post-pre	Difference in distance vision post-pre
Difference in macular thickness at 1st post-op day (Post MT-Pre MT)	1						
Difference in macular thickness at 7th post-op day (Post MT-Pre MT)	**0.83; <0.001**	1					
Difference in macular thickness at 30th post-op day (Post MT-Pre MT)	**0.86; <0.001**	**0.948; <0.001**	1				
EPT	**-0.40; <0.001**	**-0.34; 0.004**	**-0.36; 0.002**	1			
AGE(YRS)	-0.07; 0.55	-.049; 0.68	-0.06; 0.63	**0.38; 0.001**	1		
Difference in near vision post-pre	0.18; 0.11	0.06; 0.57	0.06; 0.63	-.019; 0.874	-.023; 0.850	1	
Difference in near vision post-pre	0.13; 0.26	0.18; 0.11	0.12; 0.29	**0.24; 0.03**	**0.30; 0.01**	**0.24; 0.04**	1

The numerical in the table indicate Pearson co-efficient (above) and p-value (below) to determine the co-relationship. The highlighted values indicate significant co-relationship.

The results of the above statistical analysis suggest the following:

I. The total number of participants in this study were 72 from 40-82 years of age with mean age of 61.85 and standard deviation of 9.796.

II. It consisted of 39 (54.2%) males and 33(45.8%) females.

III. There were 27(37.5%) diabetics and 45(62.5%) non-diabetics.

IV. All the participants and cataract of varying severity and roughly categorized into nuclear and cortical. Of these, 19 (26.4%) patients were NS 1+ CORTICAL +PSC and 14 (19.4%) were NS 2 + CORTICAL. Thus there were 63(86.1%) nuclear and 9(13.8%) cortical.

V. The pre-operative distant vision as measured on Snellen's chart was 10(13.9%) patients with distant visual acuity of 6/18 and rest within other categories.

VI. The pre-operative near vision as measured on Roman's near vision chart had maximum number of patients with pre-operative near vision of N6 i.e. 31(43.1%) of 72 patients. This can be explained as a result of nuclear sclerosis leading to myopic shift and thus patients having better near visual acuity. Since our study consists of more number of patients with nuclear cataract the near vision was found to be the best possible vision in majority of our patients.

VII. The post-operative distant visual acuity was found to be 6/9p in 13 (18.1%) patients and rest of them between 6/6 and CF 3 meter. Similarly, the near vision was found to be N18 in 29(40.3%) patients out of the 72 patients. This does not indicate that the near vision had detoriated. This difference was observed because when the patient had cataract, due to nuclear sclerosis there was myopic shift and hence the unaided near visual acuity was near normal. Post cataract surgery, after IOL implantation there is no phenomenon of nuclear sclerosis anymore and then the unaided near vision appears to be apparently decreased.

VIII. The EPT as measured was found to be ranging from zero to a maximum value of 47.30 seconds with mean of 15.0993 and a standard deviation of 9.86101.

IX. The pre-operative macular thickness had a minimum value of 204 and a maximum value of 340 with a mean value of 246.63 and a standard deviation of 25.948.

X. The immediate post-operative macular thickness ranged from 201 to 340 with a mean of 245.46 and a standard deviation of 20.956. The 1-week post-operative macular thickness ranged from 210 to 300 with a mean of 246.76 and a standard deviation of 23.333. The 1-month post-operative macular thickness ranged from 204 to 310 with mean of 247.22 and a standard deviation of 21.992.

It has thus been inferred from the above readings that there is no significant increase or decrease in mean macular thickness post phacoemulsification.

XI. While finding a co-relation between the difference in macular thickness and EPT it was found to be 16 % co-related. This value is significant. This showed that in 16% of the patients as the EPT increased there was a significant change in the macular thickness.

XII. Also, while comparing the 5 groups of EPT and the change in macular thickness, it was found that the highest change was observed in the participants with greater EPT. This suggests a temporal relationship of EPT and the change in macular thickness. The results were same for those found in the 1st post-op day as well as 7th and 30th post-op day. In our study we found that as the EPT increases the change in difference of macular thickness decreases. Hence, we can conclude that as EPT increase the post-phacoemulsification macular thickness decrease in our study.

XIII. It was also found that the co-relation between the change in macular thickness and age was significant on the first post-op day. This suggests that age plays an important factor in determining the change in macular thickness post phacoemulsification. The results were consistently significant on the 7th and 30th post-op day.

XIV. It was also found that while comparing the difference in macular thickness with gender, the mean difference in macular thickness increases in males and it decreases in females on the 1st, 7th and 30th post-operative day. This means that post-phacoemulsification the macular thickness increases in males and it decreases in females. The significance, however is low.

XV. While comparing the diabetic status, it was found that the mean difference in macular thickness decreased in diabetic patients while it increased by minimal value in non-diabetic patients suggesting decrease in post-phacoemulsification macular thickness in diabetics. However, this change was not significant.

XVI. While comparing the mean difference in macular thickness and cataract, it was found that the mean difference in macular thickness increased on the 1st post-operative day in case of cortical cataract and decreased in the subsequent follow-ups of 7th and 30th post-operative day. The inverse was found in cases of nuclear cataract. This means that the post-operative macular thickness in cortical cataract increases on the 1st post-operative day and decreases on the 7th and 30th post-operative day. The vice versa is true for nuclear cataracts. However, the p-value is >0.05 and hence is insignificant.

XVII. EPT also had a low co-relation (0.38) with the age of the participant, indicating that with increase in age there is increase in EPT. Hence, a temporal relationship of age and EPT was establishes with p-value of 0.001.

XVIII. Also, it was found that the difference in near vision had a relationship with EPT. We found that as EPT increases the difference also increases.

The success of phacoemulsification depends on various factors affecting the anterior and posterior segments. Of them the most important factor leading to a decreased visual acuity post operatively is macular edema.

A recent study carried out in the United Kingdom in December 2015 states that Pseudophakic macular edema occurs commonly after phacoemulsification cataract surgery, even in the absence of complications and risk factors. This large retrospective study using structured electronic medical records data quantified the risk of Pseudophakic macular edema and the risk with increasing ETDRS severity of DR. It highlights the need for prophylactic therapy, especially in those groups of eyes with the highest risk.[1]

Romero-Aroca et al[2] reported that the progression of diabetic retinopathy progressed following

phacoemulsification, especially in patients with high levels of HbA1c. also, diabetic macular edema occurred in 8 patients i.e. 6.06%. Pseudophakic macular edema developed in 2 eyes (1.52%).

A multicentre study carried out in UK showed baseline incidence of PME in eyes without operative complications, diabetes, or risk factors was 1.17% in un complicated cataract surgeries. The risk increased with presence of retinal diseases like retinal vein occlusion, retinal detachment and in patients with capsular rupture or vitreous loss.[3]

A retrospective study carried out in Korea reviewed the records of 104 diabetic patients who underwent cataract surgery and stated that 18% of diabetic patients developed increase in macular thickness > 30% after cataract surgery.[4]

Post phacoemulsification macular edema is rare, preventable and an important factor leading to visual loss post-surgery. Various factors are responsible for it- they are classified into ocular (e.g. Uveitis), systemic (e.g. diabetic) and iatrogenic (delivering high power for a longer duration during surgery). The detection of CME can be either through clinical examination, angiographic examination or OCT. the incidence

of CME measured by OCT and fluorescein angiogram after an uneventful cataract surgery is up to 41% and 30% respectively.[5,6]

Post phacoemulsification macular edema is a preventable cause of reduced vision. And hence, at our set-up we usually take steps to prevent it for example pre-operative instillation of 0.4% ketorolac tromethamine eye drops has been proven to reduce the incidence of CME.[7]

The above study was undertaken at ophthalmology department of a tertiary care hospital in the western province of India. The 72 study subjects included are those undergoing phacoemulsification for cataract. These patients were selected irrespective of their age, gender, diabetic status, choice of IOL to be implanted, etc. They were then categorised and examined for visual acuity and macular thickness before and after phacoemulsification.

In our study, the subjects varied from 40 to 82years of age. Both males and females were included in our study. There were total 72 patients of which, 39(54.2%) were males and 33(45.8%) were females. The mean age of our participants was 61.85 years. The pre-operative and post-operative macular thickness of these participants was measured on OCT. The difference was then calculated. This difference was co-related with age, gender, diabetic status, EPT, cataract grading and vision.

The participants were both diabetics and non-diabetics. Of these 72 participants, 27(37.5%) were diabetics and 45(62.5%) were non-diabetics. The blood sugars of all our patients were well controlled as a part of our pre-surgical requirement.

The cataract status of our patients included both nuclear as well as cortical. Of the, 62(86.1%) were nuclear and 10(13.8%) were cortical.

The patients then underwent phacoemulsification and the effective phaco time (EPT) was noted. 72 observations of EPT were noted and of them the mean value was 15.0993 seconds. The EPT was then grouped at an interval of 5 seconds to find the correction of the group corresponding to the highest change in macular thickness.

In this study, significant negative co-relation was found with the change in macular thickness and age on the first post-operative day. This co-relation decreased gradually in the 1st week and month. However, several factors should be taken into account as several studies show a physiological decrease in macular thickness as the age advances. A Korean study states that the central subfield thickness, average inner macular thickness, and overall macular volume were significantly lower in the female subjects. As age increased, average inner macular thickness, average outer macular thickness, overall average macular thickness, and macular volume decreased significantly.[8] However, no such significant relationship was found in our study.

A temporal relationship between age and EPT was also established. This suggests that as the age increases the EPT increases.

The cataracts were divided into nuclear and cortical. Depending, on the grading of cataract it was expected that the macular changes would be more prominent with the more advancing and mature cataracts. But, on the contrary, it was surprising to see that there was no co-relation between the cataract grading and the change in macular thickness. However, combining both- cortical and nuclear cataract showed that they were significantly co-related to the difference in macular thickness on the first post-operative day. This co-relation became weak in the first post-operative

week and was negligible in the first post-operative month.

The diabetic participants were started on the pre-operative instillation of NSAIDs eye drops as well as maintained strict sugar control. Also, NSAIDs are continued in the post-operative period reducing inflammation and thus the chances of CME are reduced. This might be one of the few reasons that the study could not establish a significant co-relationship with the diabetic status and change in macular thickness. Various studies as mentioned previous stated that the macular thickness post phacoemulsification increases specially in diabetic patients as a result of CME. Contrary to various studies, a study conducted in Detroit stated that the mean macular thickness increased in both diabetics and non–diabetics following cataract extraction as measured by OCT. These measured changes were statistically significant but the visual acuity improved in all patients, indicating minimal effect on clinical outcome as measured by visual acuity in the early postoperative period.[9]

In our study, significant co-relation of change in macular thickness was found to be with EPT. We found that there was 16% co-relationship between EPT and the change in macular thickness. This co-relation was inverse to each other and hence once can say that in 16% of the cases as the EPT rises the macular thickness difference decreases. Contrary to our studies, some studies stated that EPT showed no relationship with macular thickness and that the delivered ultrasonic energy onto the retinal structures was low and phaco was safe for retinal structures.[10]

We also divided the EPT into 5 groups of 10 seconds each. The maximum frequency corresponded to 10.1 to 20 seconds. The maximum associated change in macular thickness immediately post-operative was found to be in group 3 i.e. 20.1 to 30seconds. With higher EPT the frequency of observations decreased and hence needs to be further evaluation for obtaining useful results. Similarly, post 1week results showed maximal change in macular thickness in group 3.

While cross tabulating our variables, we found a low positive co-relation between age and EPT. This suggests that as the age increases the EPT gradually rises. However, this further requires to be evaluated on a larger sample size to be able to come to some results. Also, low positive co-relation of difference in distant vision (i.e. difference of pre and post-operative distant vision) with EPT and age was found. This suggests that as EPT and age increases the difference of distant vision increases.

Since the pre and post macular thickness do not exhibit significant change, no significant relationship with vision was established. Also, it can be explained by the presence of unaided visual acuity of 6/6p and N6 in the immediate post-operative period. This may also be a result of our skilled surgeons. The co-relation of EPT and macular thickness was established and hence it may be concluded that since all of the surgeries were carried out by experienced surgeons the EPT would be less and hence the chances of developing macular edema will be less.

However, since the sample size is relatively small as compared to the research being carried out, it requires further data collection and evaluation to conclude to a significant study.

CONCLUSIONS:
In our study, OCT proved to be a very useful tool in assessing macular thickness before and after phacoemulsification. Also, the comparison showed that the change in macular thickness was co-related with EPT. Post-operative CME, especially in diabetic patients can cause visual loss and can be prevented by the use of topical NSAIDs, strict sugar control and close monitoring of visual acuity & macular thickness. The change

in macular thickness after phacoemulsification is not related with age, gender or cataract grading in our study.

Early detection and prevention of complications of CME can improve the visual rehabilitation of the patient.

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