



COMPARATIVE ANALYSIS OF EFFECT OF CLEAR CORNEAL INCISION SITE ON TEAR FILM FOLLOWING PHACOEMULSIFICATION SURGERY

Ophthalmology

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ABSTRACT

PURPOSE- To study tear film changes after phacoemulsification surgery and to investigate effect of location of clear corneal incisions on tear film tests after surgery.

METHODS- We enrolled 50 eyes of 50 patients with senile cataract requiring phacoemulsification in a prospective randomized study. Surgery was performed with Superior clear corneal Incision in 25 patients and with temporal clear corneal Incision in another 25 patients. All patients were studied using ocular surface disease index (OSDI) score 3 days before cataract surgery and 7 days, 1 month and 3 month Post operatively. Tear break-up time (TBUT), Schirmer-1 (ST-1) and Conjunctival impression cytology to study mean goblet cell density from the corresponding conjunctival region and lower lid covered region were carried out at the same time.

RESULTS- All the tear film tests studied on the eyes showed deterioration following phacoemulsification surgery. The ST 1, TBUT, OSDI and Impression cytology mean goblet cell density results differed significantly in pre and post operative examination in both the incision site groups ($p < 0.05$). The results of these tests were not statistically significant different according to incision location ($p > 0.05$). Mean goblet cell density showed significant deterioration in inferior region as compared to superior and temporal region ($p < 0.05$).

CONCLUSIONS- Phacoemulsification can cause or aggravate dry eye symptom and affect the tear film tests values in the post operative period upto 3 months however, the location of the clear corneal incision had no effect on the tear film tests.

KEYWORDS

Phacoemulsification, Dry Eyes, Corneal nerves, incision site

Introduction

“Dry eye is a multifactorial disease of the tears and the ocular surface that results in symptoms of discomfort, visual disturbance and tears film instability, with potential damage to the ocular surface. It is accompanied by an increased osmolarity of the tear film and inflammation of the ocular surfaces described in the International Dry Eye Work Shop (2007).”¹ Incidence of dry eye in India amongst out patients has been estimated to be around 0.46% with a male: female ratio of 1:1.2.² Age related cataract cannot usually be prevented, however, cataract surgery is one of the most cost-effective interventions in the field of ophthalmology, resulting in almost immediate visual rehabilitation.³ Particularly, phacoemulsification is increasingly applied in the management of cataract patients because of its earlier refractive stabilization, reduced induced astigmatism and milder postoperative inflammation; all resulting in faster visual rehabilitation. It has been shown that improvement in visual acuity following cataract surgery is accompanied by considerable gain in real life activities, emotional and social life components.⁴ despite excellent postoperative gain in vision for most patients, many are dissatisfied because of tear film dysfunction⁵⁻⁸ poor near vision⁹ and reduced contrast sensitivity.¹⁰

Tear film dysfunction after cataract surgery due to the use of topical medications, reduced corneal sensitivity and conjunctival goblet cell loss have been investigated previously by many studies.¹⁰⁻¹⁶ In our study we analyzed the effect of clear corneal incision site and tear film changes in patients undergoing phacoemulsification surgery by means of serial clinical examinations, subjective questionnaire and conjunctival impression cytology.

Material and Methods

- Study area** – Study was conducted in Dr. Baba saheb Ambedkar medical College and Hospital a tertiary care hospital catering needs of both rural and urban population.
- Study population-** Data collected from patients who came to Ophthalmology OPD and who were having cataract in one or both eye requiring cataract surgery from May 2015 to October 2015.
- Type of study:** Prospective and interventional Randomized Comparative Study.
- Sample size and sample technique:** The required sample size was 50 eyes, 25 in each group for desired power of study of 90% and level of confidence of 5%. We enrolled 50 eyes of 50 patients with senile cataract requiring phacoemulsification in this study. The patients were randomized into two groups A and B using a block randomization with sealed envelope system. Surgery was

performed with Superior clear corneal Incision in 25 patients of group A and with temporal clear corneal Incision in another 25 patients of group B.

Inclusion criteria:

- Age > 50 years.
- Patients having unilateral or bilateral age related cataract with or without dry eye Symptoms.

Exclusion criteria:

- Age < 50 years.
- Pseudophakia in the other eye.
- Cataract caused by an etiology other than age, e.g., trauma, uveitis, drug induced.
- Pre-existing ocular diseases glaucoma, disorders of lids, conjunctiva, cornea, and sclera.
- Chemical burns, radiation.
- Use of contact lens.
- Patients on chronic ocular medications.
- Patients who have undergone corneal refractive surgery.
- Patients who had ocular allergies, pterygia, meibomitis or blepharitis.
- Patients who will not consent to the study

Data collection and technique and tools- Pre and post operative assessments were performed by one ophthalmologist. The surgical notes were made inaccessible to the evaluating ophthalmologist. Pre-operative assessments included Best corrected visual acuity (BCVA) using Snellen standards, intraocular pressure and fundoscopic evaluation after pupil dilatation. Tear break-up time (TBUT), Schirmer-I test (ST-1) was measured, conjunctival impression cytology from the corresponding conjunctival region and lower lid covered region was analyzed and ocular surface disease index (OSDI) was used to evaluate patients 3 days before cataract surgery and 7 days, 1 month and 3 month Post operatively. Phacoemulsification was performed using the Infiniti Vision System (Alcon Laboratories), and the same Ultrasound and fluidic settings were used by a single experienced surgeon.

Statistical analysis

- Quantitative variables were compared using unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed.) between the two groups and Paired t-test/ Wilcoxon ranked sum test within the groups across follow-ups.
- Qualitative variable were compared using Chi-Square test

/Fisher's exact test.

Ap value of <0.05 was considered statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0

Results

There were no significant differences in demographic or ocular characteristics of the study groups at baseline (Table1). In both the groups female to male ratio was approximately 6:4. In context of best corrected visual acuity, there was no significant difference between the groups preoperatively and postoperatively. Pre-operatively the mean and standard deviation for ST1, TBUT, OSDI and Impression cytology respectively were comparable in both the groups with ($p>0.05$).

Postoperatively, The values of ST 1 deteriorated following phacoemulsification surgery with peak at one months in both the incision groups ($p<0.05$), the mean and standard deviation for Shirmers 1 at 1 week was found out to be 7.8 ± 1.32 , 6.88 ± 0.97 at 1 month and 8.08 ± 1.55 at 3 months in Group A and in Group B the mean and standard deviation for Shirmers 1 at 1 week was found out to be 7.52 ± 1.23 , 6.6 ± 0.71 at 1 month and 8.52 ± 1.16 at 3 months. However there was no statistically significant difference in ST1 values according to incision site ($p>0.05$).

Similarly, the mean and standard deviation for TBUT was found to be 7.84 ± 1.14 at 1 week, 6.68 ± 0.99 at 1 month and 6.92 ± 0.95 at 3 months respectively in Group A and for Group B mean and standard deviation for TBUT was found to be 7.36 ± 1.11 at 1 week, 6.52 ± 0.82 at 1 month and 7.52 ± 1.16 at 3 months respectively. The values for TBUT were significantly worse than before surgery ($p<0.05$), However there was no statistically significant difference in TBUT values according to incision site ($p>0.05$).(Table-2)

We observed that the post op mean and standard deviation value for OSDI score for Group A was 49.4 ± 3.54 at 1 week, 52.31 ± 3.31 at 1 month and 49.75 ± 3 at 3 months. For Group B, the mean and standard deviation for OSDI score was 50.09 ± 2.99 at 1 week, 50.56 ± 3.03 at 1 month and 49.36 ± 2.82 at 3 months. We found no statistically significant change of overall OSDI score before and after cataract surgery in both the groups ($p>0.05$). We found that Incision site had no effect on OSDI scores when compared between the two surgical groups ($p>0.05$).(Table-4)

Mean Goblet Cell Density (MGCD) - In Group A the mean and standard deviation for Mean goblet cell density in superior quadrant was found to be 200.82 ± 50.36 at 1 month and 240.78 ± 44.89 at 3 month. The mean cell density in inferior quadrant was found to be 152.33 ± 36.51 at 1 month and 160.94 ± 37.16 at 3 month post operatively. Similarly, in Group B the mean and standard deviation for Mean goblet cell density in temporal quadrant was found to be 205.35 ± 31.47 at 1 month and 250.52 ± 31.79 at 3 month. The mean cell density in inferior quadrant was found to be 155.56 ± 21.75 at 1 month and 165.2 ± 23.88 at 3 month post operatively. We found statistically significant difference between Pre op and Post op values in mean goblet cell densities in both the groups ($p<0.05$). There was no difference according to the incision site in both the groups ($p>0.05$). Although, the mean goblet cell density decreased significantly in superior, Temporal and Inferior conjunctival region after 3 months post op, but when compared with superior and temporal region mean goblet cell loss, the decrease in the mean goblet cell density in inferior region was significantly higher with $p<0.05$.(Table5)

Discussion

Cataract surgery has widely been seen to adversely affect the tear film status specially in the early postoperative period, hence leading to the development of dry eye as shown by various studies.^{5,17} At the Hawaiian Eye 2011 meeting, a report was discussed the results of a prospective multicenter study which assessed the prevalence of dry eye in 272 eyes that underwent cataract surgery. The study found that more than 60% of eyes had abnormal TBUT, 50% of eyes had central corneal staining and 21.3% of eyes had low Schirmer test results, all of which are diagnostic signs of dry eye or dry eye syndrome.¹⁸ In study by Roberts and Elie also demonstrated that a clinically significant proportion of cataract surgery patients experienced some degree of dry

eye symptoms after surgery.¹⁹

ST-1 AND TBUT

Li, et al in 2007 did a study to investigate dry eye disease and analyzed the pathogenic factors in patients after cataract surgery.^{7,15} Their study concluded that dry eye can develop or deteriorate after cataract surgery if not treated on time. Dry eye appeared at 1 week postoperatively and peaked at 1 month. Similar findings were observed by Liu, et al.¹⁷ Cho, et al.⁸ and Gharaee, et al.²⁰ Our patients had normal Shirmers 1 and TBUT findings at the onset of our study. Pre-operatively the mean and standard deviation for ST1 and TBUT were 9.8 ± 2.4 and 9.76 ± 1.74 , in patients of Group A and 9.7 ± 1.61 , 9.52 ± 1.78 , in patients of Group B respectively. The Pre op values in both the groups were comparable with ($p>0.05$).

After phacoemulsification surgery both the dry eye tests ST-1 and TBUT showed a lower value indicating that the tear production and tear film stability of the eyes were affected. The values were lowest at 1 month after which they improved; and these observations were similar to that of study by Li et al. They also stated that misuse of eye drops is one of the major pathogenic factors that causes dry eye after cataract surgery.

Study by S.Khanal, et al.²¹ also reported findings similar to our study. The probable cause is thought to be due to a decrease in tear production and increase in tear evaporation. The decrease in tear production is due to decrease in corneal sensitivity while use of steroid drops and other drops containing BKC used post operatively destabilizes the lipid layer resulting in increased evaporation.

Our observations were seconded by work of Gharee, et al. They concluded that clear corneal incision location had no effect on tear film tests, and found no statistically significant difference between the results of pre and postoperative ST 1. However TBUT test differ significantly before and after phacoemulsification.

On consideration of the pathological basis for the results of our study, the possible reason for reduced Schirmer scores seen could be the severing of corneal nerves as a result of the corneal sections.²² This could disrupt the corneal - lacrimal gland loop the LFU responsible for tear secretion, and thus reduce the same leading to decreased ST-I values.

The significant reduction in TBUT seen in our study indicates tear film instability in the operated eye, possibly resulting from either a surface irregularity at the site of the section, which induces a faster break-up of the tear film or from a decreased mucin production by the conjunctiva as proposed by Li et al.

The speculation that cutting more sensory nerves on the rich temporal meridians would have more effect on the tear film properties was not confirmed in our study. This can be explained in accordance with the newer description of corneal nerve bundles entry into the peripheral mid-stromal cornea in a radial fashion, along different meridians and parallel to the corneal surface as described by Muller et al and Ueda et al in their respective studies on anatomy of human corneal nerves.^{20,22}

OSDI

We found no statistically significant change of overall OSDI score before and after cataract surgery in both the groups ($p>0.05$). These symptoms were most distinct at 1 month but became milder at 3 months post op.

We found that Incision site had no effect on OSDI scores when compared between the two surgical groups ($p>0.05$).

This observation was seen in other studies also and is probably due to the improvement in visual acuity on one hand and ocular discomfort and environmental triggers noted on the other hand after cataract surgery. Similar to our study Li, et al. did not find any statistically significant change of overall OSDI score before and after cataract surgery.

MEAN GOBLET CELL DENSITY (IC)

We found statistically significant difference between Pre op and Post op values in mean goblet cell densities in both the groups ($p<0.05$). There was no difference according to the incision site in both the groups ($p>0.05$).

Li, et al., also recorded decrease in goblet cells and squamous metaplasia in their study. They had obtained the samples from explosive region, upper lid and lower lid covered region. Their impression cytology demonstrated that even three months following cataract surgery, goblet cells were reduced in the bulbar conjunctiva along with the occurrence of squamous metaplasia.

Conclusion

Our study concluded that symptoms of dry eye will inevitably emerge in most patients after phacoemulsification cataract surgery. Dry eye appears at 1 week postoperatively, peaks at 1 month and become milder with time. However, the location of clear corneal incision had no effect on tear film status.

Table-1 Base line Pre op tests values in Group A and group B

Pre op Schirmer 1	A	B	0.5
Mean $\pm$ Stdev	9.8 $\pm$ 2.4	9.7 $\pm$ 1.61	
Median	9	9	
Pre op TBUT			0.587
Mean $\pm$ Stdev	9.76 $\pm$ 1.74	9.52 $\pm$ 1.78	
Median	10	10	
Pre op OSDI			0.557
Mean $\pm$ Stdev	50.9 $\pm$ 6.38	50.06 $\pm$ 3.08	
Median	51.6	50.6	
Pre op MGCD Superior/Temporal			0.44
Mean $\pm$ Stdev	308.32 $\pm$ 60.41	320.54 $\pm$ 50.14	
Median	310.7	319.5	
Pre op MGCD Inferior			0.409
Mean $\pm$ Stdev	310.68 $\pm$ 50.24	320.38 $\pm$ 29.12	
Median	310.4	321.9	

Table-2 Comparison of ST-1 between Group A and B

	Group A	Group B	P value
Post 1 week Schirmer 1			0.407
Mean $\pm$ Stdev	7.8 $\pm$ 1.32	7.52 $\pm$ 1.23	
Median	7	7	
Post 1 month Schirmer 1			0.365
Mean $\pm$ Stdev	6.88 $\pm$ 0.97	6.6 $\pm$ 0.71	
Median	7	6	
Post 3 months Schirmer 1			0.075
Mean $\pm$ Stdev	8.08 $\pm$ 1.55	8.52 $\pm$ 1.16	
Median	8	9	

Table-3 Comparison of TBUT between Group A and B

	Group A	Group B	P value
Post 1 week TBUT			0.157
Mean $\pm$ Stdev	7.84 $\pm$ 1.14	7.36 $\pm$ 1.11	
Median	7	7	
Post 1 month TBUT			0.706
Mean $\pm$ Stdev	6.68 $\pm$ 0.99	6.52 $\pm$ 0.82	
Median	7	6	
Post 3 months TBUT			0.063
Mean $\pm$ Stdev	6.92 $\pm$ 0.95	7.52 $\pm$ 1.16	
Median	7	7	

Table-4 OSDI Comparison between Group A and B

	Group A	Group B	P value
Post 1 week OSDI			0.456
Mean $\pm$ Stdev	49.4 $\pm$ 3.54	50.09 $\pm$ 2.99	
Median	50.3	49.9	
Post 1 month OSDI			0.056
Mean $\pm$ Stdev	52.31 $\pm$ 3.31	50.56 $\pm$ 3.03	
Median	52.4	50.4	
Post 3 months OSDI			0.64
Mean $\pm$ Stdev	49.75 $\pm$ 3	49.36 $\pm$ 2.82	
Median	50.3	49.4	

Table-5 MGCD Comparison between Two Groups A and B

	Group A	Group B	P value
Post 1 month MGCD Superior/Temporal			0.705
Mean $\pm$ Stdev	200.82 $\pm$ 50.36	205.35 $\pm$ 31.47	
Median	198.5	206.7	

Post 1 month MGCD Inferior			0.923
Mean $\pm$ Stdev	152.33 $\pm$ 36.51	155.56 $\pm$ 21.75	
Median	158.2	153.2	
Post 3 months MGCD Superior/Temporal			0.322
Mean $\pm$ Stdev	240.78 $\pm$ 44.89	250.52 $\pm$ 31.79	
Median	221.5	247.8	
Post 3 months MGCD Inferior			1
Mean $\pm$ Stdev	160.94 $\pm$ 37.16	165.2 $\pm$ 23.88	
Median	179.9	167.8	

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