

A Prospective Comparative Study of Central Corneal Endothelial Cell Count After Small Incision Cataract Surgery in Diabetic and Nondiabetic in Age Matched Population

Dr. Charushila Dudule¹, Mbbs, Ms, Dr. Renu Bedi², Dr. Dinesh Kumar Bedi³.

^{1,2}Department Of Ophthalmology J.L.N. Medical College, Ajmer

²Department Of Community Medicine J.L.N. Medical College, Ajmer

Abstract:

Objectives : The aim of study is to compare the preoperative and postoperative endothelial cell counts in Diabetic and Non-Diabetics in age matched population, after small incision cataract surgery. And to study the visual outcome in age matched diabetics and non diabetics after small incision cataract surgery.

Study Design And Setting: This is a prospective, cohort, comparative study. It was carried out in the department of ophthalmology, J.L.N. Medical College and Hospital, AJMER. Two hundred (200) patients of senile cataract fulfilling the inclusion criteria were selected from the outpatient department of J.L.N. medical college, Ajmer. Patients in each group were operated by the same surgeon using similar surgical technique. These patients were divided into two groups. Group A (standard group) consisted of 100 patients who were non-diabetic and Group B consisted of 100 patients who were diabetic. After taking written consent, selected patients were admitted in the ward. A detailed history and ocular examination of all patients were done. Routine investigations including random blood glucose, HBA1C, urine complete and sensitivity test of xylocaine and sensorcaine of all the patients were done.

Study Period: May 2013- May 2014

Results: In our study pre-operative and post-operative mean ECD loss is accordingly showed gradual decline. In Diabetics Mean ECD Pre-operatively was 2610.37 ± 262.65 , on Post-operative day 7 mean ECD was 2436.26 ± 215.80 , ($p=0.0001$). On post-operative 6 weeks mean ECD was 2405.96 ± 228.41 , ($p=0.0001$) on post-operative 3 month mean ECD was 2363.35 ± 270.46 ($p=0.0001$).

In Non-diabetics Mean ECD Pre-operatively was 2588.80 ± 183.24 , on Post-operative day 7 mean ECD was 2500.50 ± 200.00 , ($p=0.0001$). On post-operative 6 weeks mean ECD was 2470.93 ± 207.92 , ($p=0.0001$). On post-operative 3 month mean ECD was 2435.27 ± 221.39 , ($p=0.0001$).

The mean ECD decreases postoperatively. In Diabetics there was 6.66% loss in ECD on Post-operative day 7, 7.83% ECD loss on post-operative 6 weeks, 9.46% ECD loss on post-operative 3 months. In Non-diabetics there was 3.41% loss in ECD on Post-operative day 7, 4.55% ECD loss on post-operative 6 weeks, 5.66% ECD loss on post-operative 3 months.

Keywords: Diabetics, Endothelial cell density, Central corneal thickness.

I. Introduction

The cornea is anterior transparent avascular coat of the eyeball and is responsible for the critically important functions of light refraction and transmittance through this window of the eye. Diabetes mellitus is associated with structural changes in corneal endothelial cells and their thickness. Many clinical evidences have shown that patients with diabetes have functional abnormalities such as a higher corneal autofluorescence, lower corneal sensitivity, greater baseline corneal thickness, less endothelial cell density, and increased endothelial permeability to fluorescein after intraocular surgery. Diabetes has a higher rate of cataract so incidence of diabetic patients undergoing cataract surgery is high. The endothelial changes and more number of diabetic patients undergoing cataract surgery make the endothelial cell loss in these patients a significant factor affecting the post-operative outcome. Evaluation of the corneal endothelium is necessary to evaluate endothelial function and functional reserve. Specular microscopy is a noninvasive photographic technique that allows visualizing and analyzing the corneal endothelium. Cataract surgery is known to change the corneal endothelial cell density and morphology. In patients with diabetes, this change is more pronounced. This prospective cohort study was conducted to assess and compare the endothelial cell loss and change in central corneal thickness (CCT) after manual small incision cataract surgery (SICS) in patients with diabetes versus age-matched patients without diabetes.

Material And Method

This is a prospective ,cohort ,comparative study. It was carried out in the department of ophthalmology, J.L.N. Medical College and Hospital, Ajmer. Two hundred (200) patients of senile cataract fulfilling the inclusion criteria were selected from the outpatient department of J.L.N. medical college, Ajmer. Patients in each group were operated by the same surgeon using similar surgical technique. These patients were divided into two groups. Group A (standard group) consisted of 100 patients who were non-diabetic and Group B consisted of 100 patients who were diabetic. Study period was from May 2013- May 2014 After taking written consent, selected patients were admitted in the ward. A detailed history and ocular examination of all patients were done. Routine investigations including random blood glucose, HbA1C, urine complete and sensitivity test of xylocaine and sensorcaine of all the patients were done.

Inclusion Criteria

Ages eligible for study: 40 Years to 70 Years
 Genders eligible for study: Both

Criteria

- Patient had visually significant senile cataract (Nuclear sclerosis grade II to IV, cortical and posterior subcapsular) and require unilateral cataract extraction followed by implantation of PMMA (polymethylmethacrylate) or foldable posterior chamber intraocular lens (PCIOL);
- Inclusion criteria for diabetes group were diabetic patients on regular hypoglycemic agents and controlled blood sugar level for three weeks prior to surgery i.e HbA1C<7%.

Exclusion Criteria :

the following categories were excluded from the study.

1. Unwillingness
2. A known /diagnosed case of glaucoma
3. H/o Uveitis/trauma
4. H/o previous ocular surgery
5. H/o any other systemic illness
6. Corneal opacity
7. Contact lens wearers
8. Age related macular degeneration

Patients of

II. Observation

In our study 200 cases were included, 100 were Diabetics and other 100 were Non-diabetics. All patients undergone small incision cataract surgery. All patients were followed on post-operative day 1, day 7, 6 weeks, and at 3 months. In each follow up operated eye was examined for visual acuity, specular microscopy and slit lamp examination

Table 1: Distribution Of Patients According To Age And Sex In Diabetics And Nondiabetics

	Male		Female	
	Diabetic	Nondiabetic	Diabetic	Nondiabetic
41-50 years	14	16	15	12
51-60 years	17	18	14	13
61-70 years	20	25	20	16
TOTAL	51	59	49	41

Table 2: Distribution according to type of Cataract

Type of cataract	Diabetics (%)	Non-diabetics(%)
Nuclear	11	15
cortical Mature	05	16
Cortical Immature		09
Hypermature	02	02
PSC	06	06
Mixed	60	52

Table 3: Distribution according to pre-operative and post-operative mean ECD in Diabetics and Non-diabetics

	Mean ECD± SD		Unpaired t test score (P -0.001)
	Diabetics	Non-diabetics	
pre-operative(A)	2610.37±262.65	2588.80±183.24	0.6735
post-operative day 7(B)	2436.26±215.80	2500.50±200.00	2.1833

post-operative 6 weeks(C)	2405.96±228.41	2470.93±207.92	2.1034
post-operative 3 month(D)	2363.35±270.46	2442.07±206.52	2.3133

Table 3: Distribution according to post-operative mean ECD loss in Diabetics and Non-diabetics

	Post-operative Mean ECD Loss (cells/mm ³) ± SD		Unpaired t test score in Diabetics (P- 0.001)	Unpaired t test score in Non-diabetics (P-0.001)
	Diabetics	Non-diabetics		
post-operative day 7 (A-B)	174.11 (6.66%)	88.30 (3.41%)	14.7182	5.2656
post-operative 6 weeks (A-C)	204.41 (7.83%)	117.87 (4.55%)	16.2694	6.5261
post-operative 3 month(A-D)	247.02 (9.46%)	146.73 (5.66%)	12.8506	8.1534

**pre-operative ECD loss (A), ECD loss at post-operative day 7(B), ECD loss post-operative 6 weeks(C) and ECD loss post-operative 3 month(D)

Table 4 : Distribution according to Mean CCT pre-operatively and Post operatively in Diabetics and Non-diabetics

	Mean CCT (□m) ± SD	
	Diabetics(N=100)	Non-diabetics(N=100)
pre-operative(A)	480.03±47.94	447.50±69.28
post-operative day 7(B)	561.88±35.62	486.12±73.78
post-operative 6 weeks(C)	546.65±36.91	477.93±65.40
post-operative 3 month(D)	522.60±38.78	464.45±62.37

Table 5: Distribution according to post-operative mean increase in CCT in Diabetics and Non-diabetics

	post operative Mean CCT increase (□m) ± SD		Unpaired t test score in Diabetics	Unpaired t test score in Nondiabetics
	Diabetics(N=100)	Non-diabetics(N=100)		
post-operative day 7(A-B)	81.62 (8.38%)	38.62 (9.07%)	17.1310	12.8654
post-operative 6 weeks (A-C)	66.62 (6.56%)	30.43 (6.11%)	15.2522	7.0995
post-operative 3 month (A-D)	42.57(2.44%)	16.52 (1.45%)	8.8523	3.8395

Table 6 : Distribution according to BCVA Pre and post-operatively on 1 week, 1 month & 3 month in Diabetics and Non-diabetics

VISUAL ACUITY (BCVA)	DIABETICS(N=100)			NON-DIABETICS(N=100)		
	Pre-op	At 1 month	At 3 month	Pre-op	At 1 month	At 3month
6/6-6/9	00%	85%	84%	00%	73%	73%
6/12-6/18	00%	15%	16%	09%	27%	27%
6/24-6/60	12%	00%	00%	87%	00%	00%
<6/60-1/60	71%	00%	00%	24%	00%	00%

III. Result & Discussion

The present study was conducted in Upgraded department of Ophthalmology, J.L.N. Medical College, Ajmer (Raj.). In our study 200 cases,100 diabetic and 100 non-diabetic with operable cataract were admitted,

examined thoroughly and relevant investigations done. All patients underwent SICS. ECD and CCT were measured pre-operatively and post-operatively on day 7, 6 weeks and 3 months with non-contact specular microscope. Age distribution in our study was 40-50 years was 23%, 51-60 years was 38% , and 61-70 years was 39% in Diabetics. In non-diabetics between 40-50 years was 26% , 51-60 years was 24 % , and 61-70 years was 50%. These findings were supported by Thakur SKD et al¹ who found that 22% patients were 40-50 yrs, 35% were 51-60 yrs, 24% were 61-70 yrs. And 14 % were 81-90 yrs in Non-diabetics.

Out of 100 patients of diabetics 51% were male and 49% females, in Non-diabetics 59% were males and 41 % females. While Thakur SKD et al¹ include 49% male and 51% females in non-diabetic. In our study 60% patients were having mixed cataract,16 % having nuclear cataract,11% having cortical mature,6% having PSC, 5% having cortical immature, and 2 % having hypermature cataract in Diabetics. Whereas in Non-diabetics 52 % were having mixed cataract,15 %having nuclear cataract,9 % having cortical immature cataract, 6 % having PSC, and 3 % having hypermature cataract. Similarly in Thakur SKD et al¹ include 74 % of patients with immature cataract,22 % with mature cataract and 4 % with hypermature cataract in Non-diabetic patients. In our study pre-operative and post-operative mean ECD loss is accordingly showed gradual decline. In Diabetics Mean ECD Pre-operatively was 2610.37 ± 262.65 , on Post-operative day 7 mean ECD was 2436.26 ± 215.80 i.e. 6.66% loss in ECD, On post-operative 6 weeks mean ECD was 2405.96 ± 228.41 i.e. 7.83% ECD loss and on post-operative 3 month mean ECD was 2363.35 ± 270.46 i.e. 9.46% ECD loss (p-0.0001) .

In Non-diabetics Mean ECD Pre-operatively was 2588.80 ± 183.24 , on Post-operative day 7 mean ECD was 2500.50 ± 200.00 i.e. 3.41% loss in ECD , On post-operative 6 weeks mean ECD was 2470.93 ± 207.92 i.e. 4.55% ECD loss , On post-operative 3 month mean ECD was 2435.27 ± 221.39 i.e. 5.66% ECD loss, (p-0.0001).

Similar results obtained by studies done in 2011 Mathew PT David S et al³ studied endothelial cell loss and central corneal thickness in patients with and without diabetes after small incision cataract surgery. They studied 153 patients in the age group 40-70 years with diabetes and age matched patients without diabetes (163) undergoing manual SICS. Pre-operative and 1 week, 6 weeks and 3 months post surgery assessments of corneal endothelial loss and change in CCT were done using specular microscopy and ultrasound pachymetry. The percentage of endothelial loss at 6 weeks and 3 month being 9.26 ± 9.55 and 19.25 ± 11.57 , respectively, in controls. The percentage of loss between 6 weeks and 3 months was found to be of significant difference in diabetic patients. (p<3.023).

In 2004 Moriguibo S et al² studied corneal changes after SICS in patients with Diabetes Mellitus shown similar results as our study. Evaluation was performed in 93 eyes with type 2 diabetes mellitus (Diabetic group) and 93 eyes in patients without diabetes mellitus (Non-diabetic group) who underwent cataract surgery. The endothelial cell losses occurring 1 day, 1 week, and 1 month after operation were 2.1%, 3.6%, and 3.2%, respectively, in the non-diabetic group and 7.0%, 7.9% and 7.2% respectively, in the diabetic group. Endothelial cell losses occurring after 1 day and 1 week were significantly higher in the diabetic group than in the non-diabetic group (after 1 day, p=0.03; and after 1 week, p=0.04).

In our study mean CCT pre-operatively and post-operatively. In Diabetics there was mean CCT of patients pre-operatively was 480.03 ± 47.94 , on post-operative day 7 was 561.88 ± 35.62 , on post-operative 6 weeks 546.65 ± 36.91 , on post-operative 3 month 522.60 ± 38.78 . And in Non-diabetics there was mean CCT of patients pre-operatively was 447.50 ± 69.28 , on post-operative day 7 was 486.12 ± 73.78 , on post-operative 6 weeks 477.93 ± 65.40 , on post-operative 3 month 464.45 ± 62.37 . The mean CCT was maximum on post-operative day 7 thereafter mean CCT decreased as compared to day 7 in both Diabetics and Non-diabetics. Similar results obtained in 2004 Moriguibo S et al² studied corneal changes after SICS in patients with Diabetes Mellitus. Evaluation was performed in 93 eyes with type 2 diabetes mellitus (Diabetic group) and 93 eyes in patients without diabetes mellitus (Non-diabetic group) who underwent cataract surgery, the corneal thickness in central area was measured before surgery and 1 day, 1 week, and 1 month after surgery. Corneal endothelial cells were counted using a non-contact specular microscope.

Mathew PT David S 2011 et al³ studied endothelial cell loss and central corneal thickness in patients with and without diabetes after small incision cataract surgery. They studied 153 patients in the age group 40-70 years with diabetes and age matched patients without diabetes (163) undergoing manual SICS. Pre-operative and 1 week, 6 weeks and 3 months post surgery assessments of corneal endothelial loss and change in CCT were done using In both the groups, an initial increase in CCT till the second post-operative week was followed by a reduction of CCT in the subsequent follow-up (6 week) and a further reduction in the last follow-up (3 month). Mikkel Hugod et al⁴ performed study showed no statistically significant difference in CV or CCT in both the groups.

Rachapalle R. Sudhir et al⁵ ,no difference was observed in the mean pachymetry values, hexagonality %, and coefficient of variation of cell size between cases and controls. Our study showed no significant association of increased endothelial cell loss depending on type of cataract, grades of retinopathy, and HBA1C levels supported by study done in 2011 Mathew PT David S et al study also looked at the risk factors in diabetes that

can lead to increased endothelial cell loss. There was no significant difference in the endothelial cell loss among various grades of retinopathy, which is comparable to other studies done on patients with diabetes with and without retinopathy after planned ECCE. There was no association between the endothelial cell loss and the HbA1C levels. The percentage of endothelial cell loss was found to be more in patients who had longer duration of surgery. But the grade of cataract was found to have no association with endothelial loss postoperatively. This observation is against various studies that consider grade of nucleus as one of the most important risk factors for endothelial cell loss. Our study showed BCVA post-operatively on 1 month follow-up. In Diabetics 85% patients having visual acuity having between 6/6-6/9, and in Non-diabetics 73% patients having visual acuity between 6/6-6/9. And 15 % patients having visual acuity between 6/12-6/18 in Diabetics, and in Non-diabetics 27% patients having visual acuity between 6/12-6/18.

BCVA post-operatively on 3 month follow up. In Diabetics 84% patients having visual acuity having between 6/6-6/9, and in Non-diabetics 73% patients having visual acuity between 6/6-6/9. And 16 % patients having visual acuity between 6/12-6/18 in Diabetics, and in Non-diabetics 27% patients having visual acuity between 6/12-6/18.

IV. Conclusion

Mean endothelial cell density decreases with age but the decrease is not statistically significant. And there is no significant variation in the two groups in respect to sex. The mean endothelial density pre-operatively was 2610.10 ± 262.65 in Diabetics and 2588.80 ± 183.24 in Non-diabetics. Post-operatively there is gradual decrease in mean endothelial cell density. Compared with non-diabetic eyes, eyes of diabetic patients showed more damage in corneal endothelial cells after cataract surgery and a delay in the post-operative recovery of corneal edema. This suggests that eyes of diabetic patients may be under metabolic stress and have corneal endothelium with lower reserve ability than non-diabetic eyes. Although normal corneal stability is maintained by the reserve function of corneal endothelial cells, surgical invasion destroys reserve ability, resulting in delay in post-operative recovery of corneal edema compared with non-diabetic eyes.

Because of advances in small incision cataract surgery, severe corneal edema rarely develops, but the protection of corneal endothelium is important for long term corneal function after intraocular surgery in eyes of diabetic patients.

Note: As per above study results of endothelial cell count and central corneal thickness in diabetes after small incision cataract surgery gradually decreases with time suggesting that diabetic patients corneas are under more metabolic stress than non-diabetic and hence more care should be taken during cataract extraction with careful preoperative endothelial cell evaluation and lowering intra operative period of surgery, use of viscoelastic substances during surgery etc. These small steps can avoid postoperative damage to corneal and reduce corneal edema and hence retention of normal corneal function.

References

- [1]. Thakur SKD ,Dan A, Singh MI , Banerjee AI, Ghosh A, Bhaduri GI : “Endothelial cell loss after small incision cataract surgery” *Nepal J Ophthalmol.* 3 (6) : 177-180 ;2011
- [2]. Morikubo S , Takamura Y , Kubo E, Tsuzuki S, Akagi Y , “ Corneal changes after small-incision cataract surgery in patients with Diabetes Mellitus”, *Arch Ophthalmol.*2004;122(7): 966-969. doi: 10.1001/archoph.122.7.966.
- [3]. Mathew PT, David S, Thomas N, “Endothelial cell loss and central corneal thickness in patients with and without diabetes after manual small incision cataract surgery”, *Cornea.*2011 Apr;30(4):424-8.
- [4]. Mikkel Hugod, Allan Storr-paulsen, Gens Christian Norregaard, Jair Nicolini, Allan Boy Larsen and Jasper Thulesen. “Corneal endothelial cell changes associated with cataract surgery in patients with type 2 Diabetes Mellitus”. *Cornea* 2011;30:749-53. doi:10.1097/ICO.0b013e31820142d9.
- [5]. Sudhir RR, Raman R, Sharma T. “Changes in the corneal endothelial cell density and morphology in patients with type 2 diabetes mellitus”: a population-based study, Sankara Nethralaya Diabetic Retinopathy and Molecular Genetics Study (SN-DREAMS, Report 23) *Cornea.* 2013;31(10):1119–1122.