

# Assessment of Corneal Endothelial Changes After Uncomplicated Cataract Extraction by Phacoemulsification for Diabetic Patients with Pre-operative different levels Of HbA1c

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## Abstract

**Background:** Worldwide, among diabetic patients, 60% complain of cataract (18 million all over the world). Furthermore, cataract is considered one of the common causes of vision loss, especially in those who are diabetic.

**Aim of the work:** The present study aims at evaluating corneal endothelial variations after uncomplicated cataract removal by Phacoemulsification for Type II diabetic patients with preoperative different levels of HbA1c.

**Patients and Methods:** In the present study 60 eyes of 60 diabetic patients have nuclear cataract grades II or III were underwent cataract extraction surgery using phacoemulsification technique.

**Results:** The mean of both Endothelial Cell Density (ECD) and percentage of hexagenality (HEX% %) dropped in all patients; this drop is significantly higher in patients with HbA1c > 7 than those with HbA1c < 7. On the other hand, the mean of the Coefficient of variation (CV%) increases in all patients; this increase is more in patients with HbA1c > 7 than those with HbA1c < 7.

**Conclusion:** Cataract phacoemulsification causes damage to the corneal endothelium in diabetics. It appeared that the injury of the endothelium of patients with HbA1c < 7 % was less than that of those with HbA1c > 7.

**Keywords:** Corneal Endothelium; Phacoemulsification; HbA1c

## 1. Introduction

Globally, more than 285 million people are diabetics. This number will increase by 2030 to reach 439 million according to the International Diabetes Federation (IDF).<sup>1</sup> Those diabetic patients presented with corneal epithelial healing problems, stromal edema following intraocular surgical procedures, and corneal endothelial problems.<sup>2</sup>

HbA1c exhibits the mean of blood glucose levels over the last 3 months. Also, it gives an idea about Diabetes management and treatment during this period. Normally, HbA1c levels are between 4 % to 6.4 %. High values > 7% give an impression of poor glycemic and metabolic control. HbA1c values < 7% are ideal for those

diabetic patients, giving an impression of good glycemic control and good metabolic rate. Also, lowering the risk of micro or macro vascular diabetes complications. HbA1c levels are not affected by daily changes in the concentration of blood glucose but reflect Levels of glucose through the last 3 months.<sup>3</sup>

Worldwide, the most common leading cause of visual disability is cataract. About 18 million people globally are complaining of cataracts.<sup>1</sup> The most well-known surgical procedure for cataract management is Phacoemulsification, an ultrasonic device oscillating at high speed, which is introduced into the eye through a tiny corneal incision, and now it provides fast visual rehabilitation postoperatively.<sup>4</sup>

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Diabetic patients are characterized by low endothelial cell count, and their endothelium is more sensitive to trauma associated with Phacoemulsification.<sup>5</sup> Thus, old diabetic patients experiencing Phacoemulsification are specifically vulnerable to more endothelial damage during surgery.<sup>6</sup>

The present study aims at assessing corneal endothelial changes for Type II diabetic patients after uncomplicated cataract extraction by Phacoemulsification with preoperative different levels of HbA1c.

## 2. Patients and methods

In the present study 60 eyes of 60 diabetic patients have Nuclear cataract grades II or III were underwent cataract extraction surgery using phacoemulsification technique and followed up in Sayed Galal hospital at Bab El Shaerya, Cairo between August 2020 and December 2021.

The patients in this study are assigned to two groups. Group A: Thirty patients diagnosed with type II diabetes (Controlled) based on medical history. Their serum glycosylated hemoglobin (HbA1c) was < 7%. Group B: Thirty patients diagnosed with type II diabetes (Uncontrolled) based on medical history. Their Serum glycosylated hemoglobin (HbA1c) was > 7%.

Before surgery, each patient underwent Glycated Hemoglobin (HbA1c) Test and fully corneal endothelium assessment using non-contact specular microscopy. After surgery, all patients had been followed up monthly-basis for a period of 3 months to assess corneal endothelial changes in relation to their different levels of HbA1c Preoperatively.

Using Topcon SP-1P (Photo 1), a full corneal endothelium assessment was performed, including Endothelial Cell Density (ECD), Coefficient of Variation (CV %), Percentage of Cell Hexagonality (Hex. %).



Figure 1. Specular microscopy (Topcon SP-1P)

To achieve the aim of present study, the utilized criteria of those 60 eyes shall be described in the following subsections.

### Inclusion Criteria:

Based on the following criteria, the 60 eyes included in the present study have been selected:

Sex: Male & Female.

Patients with type 2 diabetes mellitus without any diabetic micro or macrovascular complications.

Normal clear cornea devoid of any corneal illness, dystrophy, or degeneration.

Normal corneal endothelium: Count > 2000 cell/mm<sup>2</sup> and free from any illness.

Cataract type: Nuclear cataract grades II - III.

Exclusion Criteria:

The criteria based on which the patients will be excluded from the present study are:

Corneal Illness included (Dystrophies, degeneration, and opacities).

Ocular diseases that may affect the corneal endothelium include Glaucoma, uveitis, and pseudoexfoliation.

Endothelial count < 2000 cells/mm<sup>2</sup>.

Nuclear sclerosis or hard mature cataract.

Previous ocular trauma.

Previous Intra-ocular surgery.

Any intraoperative complications included (Vitreous loss, iris injury, ciliary body injury, and suprachoroidal hemorrhage).

Postoperative complications included (Striae Keratopathy, raised intraocular pressure, and severe anterior chamber reaction).

Surgical Technique

All cases experienced phacoemulsification surgery with an in-the-bag piece intraocular lens implantation without complications.

An INFINITI phacoemulsification apparatus (ALCON) was used to break down the nucleus in the capsular bag. The following intraoperative phaco parameters are fixed for all the patients:

P.O.C	VACUUM	FLOW RATE (CC/MIN)	POWER
PHACO 1	30	30	60
PHACO 2	300	30	40
PHACO 3	300	30	0

Phacoemulsification surgery was done for all patients with an in-the-bag piece intraocular lens implantation without complications by the same surgeon, using the INFINITI vision system (Photo 2) and a 0.9 mm ABS mini-flared 45 Kellman tip (Photo 3)



Figure 2. INFINITI vision system



Figure 3. 0.9 mm ABS mini-flared 45 kelman tip

Povidone-iodine 10% (Betadine) was used in the disinfection of eyelids, and a sterile plastic adhesive drape was used in draping the eye. Then, a wire speculum was applied, and the conjunctiva was disinfected with povidone-iodine 5%. Two side ports were done using a 20-gauge microvitrectomy blade (MVR).

Viscoelastic VISICROM 2% (20 mg Hydroxypropylmethylcellulose solution/ml) was injected through the side port to form the AC and protect the endothelium.

Regular rounded capsulherexis was done followed by Phacoemulsification of lens matter using stop and shop technique, finally single Piece IOL in bag implantation then stromal hydration of corneal wounds.

#### Postoperative Evaluation:

Specular microscopy examination was done for all patients for cell density and morphology; 1 week, 4 weeks, and 12 weeks postoperatively.

**Table 2. CD, Hex % and CV % before operation, 1 week, 1 month and 3 months after operation among cases with HbA1c < 7**

		HbA1c < 7				Test value	P-value	Sig.
		Before Operation	1 week after Operation	1 month after Operation	3 months after Operation			
CD	Mean $\pm$ SD	2781.33 $\pm$ 278.85	2435.17 $\pm$ 300.81	2519.63 $\pm$ 253.42	2586.00 $\pm$ 247.64	151.511•	<0.001	HS
	Range	2294 – 3342	1800 – 2920	1987 – 3001	2100 – 3099			
Hex.%	Mean $\pm$ SD	64.90 $\pm$ 2.78	60.00 $\pm$ 3.53	61.03 $\pm$ 3.00	61.90 $\pm$ 2.67	47.626•	<0.001	HS
	Range	60 – 69	52 – 68	55 – 67	58 – 67			
CV%	Mean $\pm$ SD	32.63 $\pm$ 2.39	36.30 $\pm$ 2.51	34.93 $\pm$ 2.26	33.87 $\pm$ 2.11	109.182•	<0.001	HS
	Range	30 – 38	33 – 42	31 – 40	31 – 39			

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant

•: Repeated Measures ANOVA test

Corneal endothelium assessment postoperatively during follow up periods; 1 week, 1 month and 3 months after the operation in terms of ECD, HEX% and CV% in those patients with HbA1c > 7 in comparison to their preoperative values of the mentioned terms of assessment as shown in [table \(3\)](#); that shows a statistical significant difference in the postoperative values than those of preoperative.

**Table 3. CD, Hex % and CV % before operation, 1 week, 1 month and 3 months after operation among cases with HbA1c > 7**

		HbA1c > 7				Test value	P-value	Sig.
		Before Operation	1 week after Operation	1 month after Operation	3 months after Operation			
CD	Mean $\pm$ SD	2735.33 $\pm$ 395.16	2232.77 $\pm$ 403.02	2289.63 $\pm$ 386.49	2341.13 $\pm$ 386.38	311.828•	<0.001	HS
	Range	2030 – 3765	1300 – 3130	1550 – 3139	1590 – 3229			
Hex.%	Mean $\pm$ SD	64.10 $\pm$ 3.01	55.00 $\pm$ 3.85	56.37 $\pm$ 3.35	57.83 $\pm$ 3.05	115.639•	<0.001	HS
	Range	60 – 69	48 – 61	51 – 62	52 – 63			
CV%	Mean $\pm$ SD	33.40 $\pm$ 2.84	41.20 $\pm$ 4.30	39.33 $\pm$ 3.82	37.90 $\pm$ 3.14	109.418•	<0.001	HS
	Range	30 – 40	35 – 50	34 – 48	34 – 47			

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant

•: Repeated Measures ANOVA test

#### Statistical Analysis

Data were collected, revised, coded, and entered into the Statistical Package for Social Science (IBM SPSS) version 23.

#### 3. Results

Patients of group (1) had an age mean  $\pm$  SD 51.8  $\pm$  5.29 years, while patients of group (2) had an age mean  $\pm$  SD 50.8  $\pm$  5.73 years. There was no statistical significance between the patients of the two groups from the age point of view (P value was 0.6899).

The population general characteristics of the study patients namely; Sex and HbA1c values are presented in [table \(1\)](#).

**Table 1. Demographic data and characteristics of the studied patients**

Total no. = 60		
Sex	Male	36 (60.0%)
	Female	24 (40.0%)
HbA1c	Mean $\pm$ SD	7.18 $\pm$ 1.79
	Range	4.4 – 11
	HbA1c < 7	30 (50.0%)
	HbA1c > 7	30 (50.0%)

Corneal endothelium assessment postoperatively during follow up periods; 1 week, 1 month and 3 months after the operation in terms of ECD, HEX% and CV% in those patients with HbA1c < 7 in comparison to their preoperative values of the mentioned terms of assessment as shown in [table \(2\)](#); that shows a statistical significant difference in the postoperative values than those of preoperative.

Table (4) shows a comparison between cases with HbA1c < 7 and cases with HbA1c > 7 regarding percentage of change of ECD, HEX% and CV% during postoperative follow up visits; 1 week, 1 month and 3 months after the operation.

Table 4. Comparison between cases with HbA1c < 7 and cases with HbA1c >7 regarding percentage of change of CD, Hex % and CV %

% of change		HbA1c < 7 No. = 30	HbA1c > 7 No. = 30	Test value	P-value	Sig.
1 week after Operation						
CD	Mean ± SD	-12.60 ± 4.05	-18.67 ± 5.81	-4.287#	<0.001	HS
	Range	-21.53 – -5.81	-35.96 – -9.26			
Hex.%	Mean ± SD	-7.49 ± 5.09	-14.07 ± 6.45	-4.007#	<0.001	HS
	Range	-18.75 – 6.35	-24.24 – 0			
CV%	Mean ± SD	11.31 ± 3.15	23.50 ± 10.13	-5.948#	<0.001	HS
	Range	5.41 – 17.65	12.12 – 63.33			
1 month after Operation						
CD	Mean ± SD	-9.37 ± 3.10	-16.48 ± 4.67	-5.367#	<0.001	HS
	Range	-14.83 – -4.59	-28.8 – -8.31			
Hex.%	Mean ± SD	-5.89 ± 4.28	-11.96 ± 5.38	-4.504#	<0.001	HS
	Range	-14.49 – 6.35	-21.21 – 1.67			
CV%	Mean ± SD	7.17 ± 3.84	17.99 ± 9.79	-5.903#	<0.001	HS
	Range	-2.86 – 12.9	9.09 – 60			
3 months after Operation						
CD	Mean ± SD	-6.96 ± 2.52	-14.55 ± 4.50	-5.825#	<0.001	HS
	Range	-14 – -3.23	-23.18 – -4.59			
Hex.%	Mean ± SD	-4.55 ± 3.65	-9.68 ± 4.75	-4.141#	<0.001	HS
	Range	-13.04 – 3.17	-17.65 – 1.67			
CV%	Mean ± SD	3.94 ± 4.30	13.84 ± 9.71	-5.300#	<0.001	HS
	Range	-7.89 – 10	5.56 – 56.67			

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant

#: Mann-Whitney test

#### 4. Discussion

Postoperatively, it was observed that corneal endothelial cell density (ECD) loss in group B is greater than in group A (3 months postoperatively). On the other hand, the mean Coefficient of variation (CV% %) in group B is significantly higher than in group A (3 months postoperatively). The mean percentage of hexagonality (HEX% %) dropped in both groups, but the decline was significantly higher in group B than in group A. So, Cataract phacoemulsification causes impairment in the corneal endothelium in diabetic patients. It appeared that the injury of the corneal endothelium of patients who have HbA1c < 7 % was less than that of those who have HbA1c >7.

These findings are consistent with studies carried out by Shultz et al.<sup>7</sup>, Goebbels M. et al.<sup>8</sup>, Ventura AC et al.<sup>9</sup>, and Mikkel H. et al.<sup>10</sup>.

In the present study, most of the decrease in Endothelial Cell Density (ECD) was at 1 week postoperatively, then the rate of decrease started to decrease at 1 month and 3 months postoperatively. This is more significant in group B than in group A, as shown in the results obtained in the present study. This finding is consistent with previous studies, which have shown that endothelial cell Density (ECD) decreases 6% to 10% Post post-phacoemulsification in diabetic patients.<sup>11</sup>

Also, Hugod et al.<sup>10</sup>; reported 6.2% loss in endothelial cell density 3 months post Phacoemulsification in those who are diabetics<sup>10</sup>, Reshama et al.<sup>12</sup>; reported 10-15% loss in endothelial cell density 6 months post

Phacoemulsification in those who are diabetics<sup>12</sup>, and lee et al.<sup>13</sup>, and Yang et al.<sup>14</sup> as well.

Endothelial Cell Density (ECD) evaluation alone is not sufficient to assess the function of corneal endothelial cells after intraocular surgery. Pleomorphism represented by Coefficient of variation (CV %) and Polymorphism represented by hexagonality (HEX%) are more sensitive to evaluate whether the corneal endothelial is healthy or not.<sup>15</sup>

In the present study, most of the increase in CV% occurred at 1 week postoperatively. Then the rate of increase decreased 1 month and 3 months postoperatively. This is more significant in group B than in group A, as shown in the results obtained from the present study. This is consistent with Schultz et al. in 1986, who reported increase in the Coefficient of variation (CV%) 3 months post phacoemulsification in those who are diabetics<sup>7</sup> and Adel Abdllrahman Osman et al. who revealed Increase in CV% 1 month post Phacoemulsification compared with preoperative values and recorded the most decrease 3 months post-surgery compared to 1 month post-surgery.<sup>16</sup>

In the present study, most of the percentage of cell hexagonality (HEX. %) decreases occurred at 1 week postoperatively, and then the rate of decrease starts to decrease 1 month, 3 months postoperatively. This is highly significant in group B more than group A as shown in the results obtained from the present study.

Itoi et al.<sup>17</sup>, Yang et al.<sup>14</sup> and Akram Khan et al.<sup>18</sup> and Reshma Balan et al.<sup>12</sup> reached the same findings mentioned above. While Morikubo et al. found significantly lower HEX% values



postoperatively as compared to preoperative values<sup>19</sup>, Hugod et al. found significantly lower HEX% values postoperatively as compared to preoperative values.<sup>10</sup>

On the other hand, it is inconsistent with Lee et al. who has 6 months follow up period in assessment of corneal endothelium in diabetic patients who underwent cataract extraction using Phacoemulsification.<sup>13</sup>

Finally, Related to gender, no statistically significant difference was found between males and females in the present study. Also, no statistical significance of the influence of sex on corneal endothelium cell parameters as well as HbA1C values. This is illustrated and consistent with Kaji et al in 2000, which also allowed the influence of sex on corneal endothelium cell parameters. No significant relationship was observed in this study.<sup>20</sup> On the other hand, this is inconsistent with Sneligen et al. in 2001 in South Asia.<sup>21</sup>

#### 4. Conclusion

Diabetic patients who underwent Phacoemulsification were particularly vulnerable to greater endothelial damage during surgery. It appeared that the damage to corneal endothelium in diabetics with HbA1c > 7 was more than that in those with HbA1c < 7.

#### Disclosure

The authors have no financial interest to declare in relation to the content of this article.

#### Authorship

All authors have a substantial contribution to the article

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There are no conflicts of interest.

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