

To study changes in corneal thickness and corneal endothelial cell density after phacoemulsification cataract surgery

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Abstract: *Cataract is common cause of diminution of vision. Myopia can be related to cataract. The common surgery of cataract performed is Phacoemulsification with the placement of an intraocular lens in posterior chamber. With the newer devices like specular microscopy, we can add to the existing literature. To study and compare thickness of central corneal (CCT) earlier and later of phacoemulsification surgery. To study and compare endothelial cell density (ECD) earlier and later of phacoemulsification surgery. An observational cross-sectional study with 120 patients will be conducted in hospital-based setting utilizing the data of patients' eye. The relationship between preoperative and post-operative findings of CCT and ECD will be analysed by using specular microscopy. The mean ECD is expected to be lower than that of preoperative value and the mean CCT is expected to be higher than pre-operative value. The Pearson correlation test will be used to compare findings of ECD and CCT preoperative and postoperative. The primary result which is to be calculated will be change in corneal ECD (cells per square millimetre of the corneal surface) which is expected to be decreased. The central corneal thickness (CCT) will be calculated in micrometers is the another result which is expected to be increased.*

Keywords: *Endothelial cell density, central corneal thickness, specular microscopy*

I. Background/rationale

The cause of diminution of vision is Cataract, characterized by the blurring of normal lens which is transparent and crystalline by nature, resulting in incomplete to complete loss of vision. Though mild grade of cataracts can be managed by prescribing those patients glasses. In long period, it is managed by surgery (1-3). The common surgery done for cataract is Phacoemulsification surgery with the placement of a lens which is placed behind the iris. Though phacoemulsification can cause endothelial cells loss during cataract surgery, which results in corneal edema. The endothelium is composed of a cell layer which are hexagonal in shape. The pump activity of endothelial cells of the cornea helps it to sustain in dehydrated state. This guarantees its transparency. This dynamic event is managed by Na⁺/K⁺-ATPase pump. There is a gradient across the corneal endothelium of bicarbonate ion. To maintain the pump activity, a minimal of 400–500 cells/mm² is compulsory. Failure of working of pump causes corneal decompensation and diminution of vision (4-8). Endothelium do not

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have the ability to regenerate which causes the endothelium to become gradually decrease in number of cells. After any intraocular surgery or any ocular disease, the cell loss becomes worsened. By the age of 3 years the cornea attains the thickness of the adult cornea. Subsequently there is a decrease in the thickness of cornea which is gradual but is insignificant. During surgery reasonable damage of the corneal endothelium can cause a temporary corneal thickness increment. Some authors have found that preoperative values were returned after 4 weeks in all patients, whereas others have reported sustained increase upto 6 months postoperatively. Specular microscopy is a non-invasive microphotographic technique that analyze the corneal endothelium. Modern specular microscope evaluate the size, shape and population of the endothelial cells. Lundberg et al., claimed in their study that there is a substantial corneal edema postoperatively which is accompanied with a loss of corneal endothelial cell. (9-13)

The main rationale of this study is to assess endothelial cell density loss and thickness of central cornea preoperatively and then postoperatively and to assess decline in endothelial cell density due to phaco influencing the central corneal thickness.

Objectives-

- To study and compare central corneal thickness preoperatively and postoperatively
- To study and compare endothelial cell morphology and density before and after phacoemulsification surgery.
- To determine the factors leading to loss of corneal endothelial cells during phacoemulsification surgery.

II. Methods

Study pattern: this is a hospital based Observational cross sectional study.

Settings: All the procedures and surgery will be conducted at the department of ophthalmology, AVBRH, Sawangi, by an experienced surgeon under standard preoperative conditions.

Duration of study: 2 years from October 2018 to October 2020.

Participants: The patients who are undergoing cataract surgery at AVBRH will be selected for study after taking the inclusion and exclusions criteria into consideration.

Inclusion criteria

Patient's age: 50-70 years old;

Senile cataract with nuclear sclerosis between 1 to 3.

Exclusion criteria

Patient not giving consent

Diabetic patients.

Complicated cataract

Traumatic cataract.

Number of endothelial cells less than 2000/ mm²

Ocular diseases like Glaucoma, Corneal dystrophy other corneal diseases.

Mature senile cataract/ Hyper mature senile cataract/ grade 4 nuclear sclerosis.

Patient with intra operative complications during cataract surgery.

Pseudo exfoliation syndrome.

Variables: The variables to be studied are age of patients, gender distribution of patients, endothelial cell density, central corneal thickness, hexagonality.

Data sources/ measurement: The study will be adhered to the tenets of the declaration of Helsinki, and will be approved by the Institutional Ethical Committee (IEC) of DMIMS (DU).

All patients will be explained about the details and risk involved in the procedure and each patient will be informed about the consent before his or her inclusion in the study.

The patients fulfilling the inclusion criteria will be sequentially recruited for the study. Detailed history will be taken and complete ocular examination will be conducted, including specular microscopy.

All surgeries will be performed by the single surgeon who is trained in phacoemulsification technique by using the same surgical technique (using Carl Zeiss Visalis phacoemulsification machine).

Every patient's pupil will be dilated by putting one drop of tropicamide 1% with phenylephrine 2.5% in every 15 min for 45 min. The steep meridian is marked with the surgical marking pen. Anaesthesia will be given through peribulbar route. The eye and surrounding area will be made sterile by 5% povidone iodine solution and the sterile drape will be put. Wire speculum will be inserted and wash to conjunctiva will be given. 2 Side port will be made with MVR blade. Then viscoelastic agent will be used to fill anterior chamber. Anterior capsulotomy was done by continuous curvilinear capsulorhexis method using 26 no. needle cystitome. For steep vertical meridian, superior self-sealing, tunnel incisions made on cornea which is starting at mid limbus at 12 o'clock position using 3.2 mm keratome knife with surgeon sitting at head end. For steep horizontal meridian, temporal self-sealing, 3 step incision made on cornea will be made at the temporal side of eye using 3.2 mm keratome with surgeon sitting temporally. Hydrodissection and hydro delineation will be done. Nucleus is rotated freely in capsular bag. Phacoemulsification of nucleus will be done by flip and chop method. Remaining cortex will be aspirated by bimanual irrigation and aspiration. Foldable intraocular lens will be placed inside the bag of capsule by injector. Anterior chamber wash will be given. Main incision and side ports will be sealed by hydration. Antibiotic eye drop (Moxifloxacin 0.5%) was instilled and eye was padded.

Bias: There was a potential for observer bias in this study which was standardized by observing observer/investigator to record the data. All variables will be recorded by a standard protocol which will be strictly followed thus eliminating bias due to faulty data. The CCT will be measured by using specular microscopy, before surgery and one day, on 4th week, and on 12th week after surgery. The CCT will be measured with the patient seating upright. Average of Three readings will be taken. The measurements will be noted by same observer. The density of endothelial cell will be measured using a non-contact specular microscope before surgery and on one day, on 4th week, and on 12th after surgery. For counting endothelial cells, central method will be used. Using fixed frame technique by using photograph, around 20 to 30 cells will be counted. The average of three fields which are central will be calculated.

Study size: using sample size formula with desired error of margin

$$N = \frac{(z\alpha/2)^2 P(1-P)}{d^2}$$

Quantitative variables: The quantitative variables are endothelial cell count, central corneal thickness.

Categorical variables will be specified as number and percentage of patients and by using Pearson's Chi-square test other groups are compared.

Calculation of decline in endothelial cell density

Endothelial cell loss(ECL) = (preoperative cell count- postoperative cell count/preoperative cell count) ×100 to express as percentage decrease.

Accuracy of central corneal thickness measurement can help as a scale for measuring endothelial function in corneas having unhealthy endothelium or with marginal low endothelial cells.

Statistical methods:

The normal distribution of each continuous variables will be assessed by using descriptive and inferential statistics using student paired t test and Pearson correlation efficient and chi square test. P less than 0.05 is considered as level of significance. 5% of alpha level will be taken, i.e., if any $p < 0.05$ it will be significant statistically.

Expected outcomes

The main outcome will be a cell count change or density of corneal endothelial (cells per square millimetre of the corneal surface). There could be increase in corneal cell area to compensate corneal endothelial cell loss.

The central corneal thickness (CCT) which is calculated in micrometres will be secondary result. This is expected to be increased in immediate postoperative day 1, and then it is expected to be decreased and comes to preoperative value by 12th week. The corneal edema occurring due to damage to corneal endothelium because of phacoemulsification surgery, could explain the increase in CCT which is precisely detected in patients having higher endothelial cell loss. Lundberg et al., also showed a similar result in which loss of endothelial cells is associated with a corneal edema due to surgery (1).

III. Discussion

Key results: A significant decrease of endothelial cell density will be seen in all participants. In a cataract surgery without intraoperative complications, loss of endothelial cells may be due to vibrations caused by ultrasound, air bubbles, solution used for irrigation. The main outcome which is to be measured is a change in corneal endothelial cell count. The corneal cell area could increase to compensate in due to corneal endothelial cell loss. A higher energy used during surgery gets translated into more loss of endothelial cells.

The central corneal thickness is the second result which is expected to be increased in immediate postoperative day1, and then it is expected to be decreased and comes to preoperative value by 12th week. The corneal edema occurring due to damage to corneal endothelium because of phacoemulsification surgery, could explain the increase in CCT which is precisely detected in patients having higher endothelial cell loss. A healthy cornea compensates quickly for temporary increase in central corneal thickness after phacoemulsification surgery. There is a study done by Kohlhaas et al who stated that there is no endothelial cells loss after 4 weeks of phacoemulsification which might propose that by this time there is healthy wound.

In a study done by Pirazzoli, surgery is associated with loss of endothelial cell which is directly linked with the trauma occurring to endothelium during surgery (5).

The study has expected outcome of a decrease in the percentage of hexagonal cells at postoperatively. A similar study done by Lee et al. Morikubo et al. also quoted alike results.

A number of different articles related to factors involved in the discussion of this study were reviewed (14-70).

Limitations –

- Since our sample size is small further larger scale studies are required to confirm findings.
- Relations of multiple other factors to postoperative outcome could have been studied if the study was of longer duration.
- Loss of follow up of patients.

Interpretation : the decrease in endothelial cell count is directly associated with damage occurring to endothelium cell during surgery.

Generalizability- Variables have been considered in this study with efforts to minimize bias to greater extent. A larger scale of study involving a larger population can be carried out and some few more variables can be considered to further validate the results of the present study.

IV. Conclusion

Accurate measurements of thickness of cornea may help in evaluating overall function of endothelial cell with a unhealthy endothelium or with low endothelial cell counts. Overall, the endothelial cell loss occurs as an unavoidable sequel of phacoemulsification

Central corneal thickness first increases then decreases values are normalized to preoperative value by 12th week. CCT was used as a substitute indicator for endothelial function. This is because a well-effective endothelium keeps the corneal stroma in an active state.

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